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Part II

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40 CFR Part 79
Fuels and Fuel Additives Registration Regulations: Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 79

[FRL-4121-4]

Fuels and Fuel Additives Registration Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice presents proposed regulations for the registration of motor vehicle fuels and fuel additives as authorized by sections 211(b)(2) and 211(e) of the Clean Air Act (CAA). Under the proposed regulations, producers of motor vehicle fuels and fuel additives would be required to conduct certain tests and submit information regarding the composition of emissions produced by such fuels and fuel additives and the effects of these emissions on the public health and welfare. Additional provisions for determining the effects of fuels and additives on the performance of vehicular emission control devices would be coordinated with existing and future rules under section 211(f). The proposal includes a grouping system and other mechanisms designed to avoid duplicative efforts and reduce the costs of testing by producers of fuels and fuel additives.

The proposed regulations would supplement existing registration requirements, and would potentially apply to both current and future fuels and additives. The proposed new requirements are designed to provide a body of information that would assist EPA in evaluating the potential adverse effects of various types of fuels and fuel additives and in determining whether futher risk assessment or regulatory action is needed under section 211(c).

DATES: Written comments on this Notice of Proposed Rulemaking (NPRM) will be accepted until June 30, 1992. A public hearing will be held May 28, 1992 at 9 a.m. It will be extended to May 29, if necessary, but prospective presenters should be prepared to testify on the first day.

ADDRESSES: Comments on the NPRM should be submitted in duplicate to: EPA Air Docket (LE-131); Attention: Docket No. A-90-07; U.S. Environmental Protection Agency, room M-1500, 401 M Street SW., Washington, DC 20460; phone (202) 382-7548. This docket is located at the above address on the first floor of Waterside Mall and is open for public inspection weekdays from 8:30 a.m. to 12 noon and from 1:30 p.m. to 3:30 p.m. As provided in 40 CFR part 2, a reasonable fee may be charged by EPA for copying services. The public hearing will be held in Ann Arbor, Michigan at the Ann Arbor Regent—Best Western Domino's Farms Hotel and Conference Center, 3600 Plymouth Road (U.S. 23 at Plymouth Road); phone (313) 769-9800.

FOR FURTHER INFORMATION CONTACT: Mrs. Carolyn Krueger, SDSB12, Regulation Development and Support Division, U.S. Environmental Protection Agency, 2565 Plymouth Road, Ann Arbor, MI 48105; phone (313) 668-4274. Persons who wish to receive a copy of the regulatory text for this proposed rule (including the proposed health testing guidelines) should leave a message, including their name, complete mailing address, and telephone number, at (313) 668-4361. The proposed regulatory text is also available in the public docket referenced above.

SUPPLEMENTARY INFORMATION:

I. Public Hearing

Any person interested in presenting testimony at the public hearing should notify the contact person listed above at least seven days prior to the day of the hearing. The notification should include the estimated time required for the presentation and identification of audio/visual equipment needs, if any. A sign-up sheet will be available at the registration table the morning of the hearing for scheduling the order of testimony. It is suggested that sufficient copies of the statement and other presentation materials be brought to the hearing for distribution to the audience. All materials submitted will be made part of the official record for this rulemaking.

Mr. Richard D. Wilson, Director of the Office of Mobile Sources, has been designated as presiding officer for the hearing. The hearing will be conducted informally, and technical rules of evidence will not apply. Written transcripts of the proceedings will be made by a court reporter. Copies will be available for examination in the public docket or for purchase by individual arrangement with the court reporter.

II. Background

A. Introduction

Over 2,200 fuels and 4,100 fuel additives are currently registered with EPA and, to some degree, each of them produces emissions which may contribute to potentially harmful air pollution in the United States. The primary purpose of this proposed rulemaking is to establish registration requirements which will provide information for identifying and evaluating the potential adverse air pollution effects of motor vehicle fuels and fuel additives and for guiding the direction of related regulatory actions in the future.

The remainder of this section reviews the statutory history of this proposed rulemaking, summarizes the public comments received in response to the Advanced Notice of Proposed Rulemaking, and defines certain key terms used in later discussion. The overall scope of the program is described in section III. Section IV outlines the objectives, rationale, and implementation of the proposed grouping system for fuels and additives. Issues germane to the generation of fuel/additive emissions for subsequent testing are discussed in section V, and proposed requirements for evaluating the effects of fuels and additives on the public health and welfare are described in section VI. Section VII outlines the proposed reporting requirements for the program. Subsequent sections discuss special program provisions, compliance considerations, confidentiality issues, public participation, and administrative topics.

B. Statutory History

Section 211(a) of the Clean Air Act (CAA), 42 U.S.C. 7545, authorizes EPA to designate any motor vehicle fuel or additive and prohibits producers of designated fuels or additives from selling such products unless they have been registered by EPA in accordance with section 211(b). The basic data elements which producers of fuels and additives must submit for purposes of registration, as stipulated by section 211(b)(1), include commercial identifying information, range of concentration, purpose-in-use, and chemical compostion. EPA issued regulations implementing this provision in 1975 (40 CFR part 79).

The 1970 CAA also provided EPA with discretionary authority to establish additional requirements for fuel and fuel additive registration. According to section 211(b)(2), EPA "may also require" producers "to conduct tests to determine potential public health effects of such fuel[s] or additive[s] (including, but not limited to, carcinogenic, teratogenic, or mutagenic effects)," and to furnish other "reasonable and necessary" information to identify fuel and fuel additive emissions and determine their effects on vehicular emission control performance and on the public health and welfare. The statute further stipulates that testing for health effects is to be conducted

according to procedures and protocols established by the Administrator, and that test results will not be considered confidential. When the producer has submitted the required information and has given assurances that the Agency will be notified of future changes in that information, section 211(b)(3) directs the Administrator to grant registration to the fuel or additive.

EPA did not exercise its discretionary authority to require fuel and additive testing under section 211(b)(2) when the general registration regulations under section 211(b)(1) were issued in 1975. However, in the CAA Amendments of 1977 (Pub. L. 95–95, August 7, 1977), Congress added section 211(e) to the statute, which made implementation of section 211(b)(2) mandatory and contained additional provisions concerning the implementation of the statute.

Section 211(e)(1) requires implementation of the section 211(b)(2) authority within one year of enactment of the 1977 amendments. In an effort to fulfill this requirement, EPA published an Advanced Notice of Proposed Rulemaking (ANPRM) in 1978 (see 43 FR 38607, August 29, 1978; Docket ORD–78–01); however, the rulemaking did not go forward during the next ten years. Nevertheless, this action has remained on the EPA regulatory agenda, and a development plan for the rulemaking was created in 1988.

C. Recent Events and Agency Actions

In 1989, a citizens group brought a lawsuit (*Thomas* v. *Reilly*, C.A. No. 89–6269 [D. Oreg. 1989]) challenging EPA's failure to promulgate fuel and fuel additive testing regulations within the one-year time limit permitted by CAA section 211(e). EPA entered into a consent decree in settlement of this lawsuit without adjudication of any issue of fact or law. The consent decree, which was signed by the Court, required that the EPA Administrator sign an advance notice of proposed rulemaking by August 1, 1990, a notice of proposed rulemaking by January 1, 1992, and a final rule by June 1, 1993. The decree did not address "the substance of the rulemaking," nor did it "limit or modify the discretion accorded * * * by section 211 * * * or general principles of administrative law in any fashion". By agreement with the plaintiff, the NPRM signature deadline was later extended to April 1, 1992.

The Agency published the required ANPRM on August 7, 1990 (55 FR 32218). A public hearing was held on September 26, 1990, followed by a 30-day period for written commentary. Public reponse included four oral presentations at the hearing and the subsequent submission of 24 written comments.

To gain further public involvement in the rulemaking, the Agency engaged the services of a private consultant group to assess the feasibility and appropriateness of applying regulatory negotiation procedures (under the provisions of section 583 of the Negotiated Rulemaking Act of 1990) to the development of the section 211 regulations. During the months of March and April, 1991, the consultants interviewed representatives of a variety of affected industry groups and environmental organizations to gauge their level of interest in the program and their willingness to participate in potential negotiations. These parties were also invited to a meeting in Washington, DC on May 2, 1991, to discuss the program issues further and to explore the potential advantages and disadvantages of a formal regulatory negotiation process. Susbsequently, the meeting attendees were polled again about their willingness to enter negotiations. The results indicated that there was insufficient support among a number of key parties, and EPA thus decided not to convene a regulatory negotiation for this proposed rulemaking.

D. Summary and Analysis of Comments

1. Program Focus and Jurisdictional Issues

The overall focus and scope of the potential new registration requirements were frequent topics of public comment received in response to the ANPRM. With respect to provisions in section 211 concerning the public health and welfare impacts of fuels and fuel additives, nearly all respondents recognized that information and testing requirements related to fuel and additive emissions were mandated by the statute. However, not all respondents agreed about the propriety, necessity, and desirability of requirements for the conduct of tests on the "raw" (i.e., uncombusted liquid) fuels and additives themselves. The majority maintained that the underlying objectives of the Clean Air Act and the specific language of section 211 would best be met by restricting the focus of the regulations to fuel and fuel additive emissions. According to these respondents, requirements addressing the potential adverse effects of "raw" fuels and additives would not help to elucidate the sources and effects of air pollution, and would thus fall outside the scope of the statute. A few commenters held the opposite point of view, arguing for broad and comprehensive health testing of fuels and additives in their original liquid formulations as well as in the combusted and vaporized states.

As discussed more fully in section III.B of this NPRM, EPA believes that the Agency has some discretion under section 211 to determine the focus of fuel and additive evaluation requirements. Consistent with the goals of the CAA, EPA has decided to focus this proposed rulemaking on the emissions-based effects of fuels and fuel additives. Thus, the proposed health effects testing provisions specifically address the effects of inhalation exposure to fuel and additive emissions, inculding both evaporative and combustion emissions. Tests to determine the direct toxicity of "raw" fuels and additives (e.g., by oral or dermal exposure) are not included except insofar as such information may be needed to determine the effects of their emissions. The Agency believes this focus to be compatible with the intent of Congress and the scope of authority granted by section 211.

Focusing today's proposed rulemaking on the emissions of fuels and fuel additives will also serve to relieve concerns about possible areas of overlap between section 211 and other Federal regulatory programs. Existing authority under the Toxic Substances Control Act (TSCA), 15 USC section 2601 *et seq.*, has often been cited in this regard. TSCA provides EPA authority to examine the potential environmental and health risks associated with chemical substances or mixtures, and several respondents felt that promulgation of the health effects testing provisions in section 211(b) would be duplicative of the regulatory mechanisms already in effect under TSCA. While rejecting the notion that TSCA might eliminate the need for implementation of section 211(b), EPA recognizes the need for coordination between the two programs.

To a large extent, the potential overlap between TSCA and section 211 is more legalistic than programmatic, and need not result in overlapping regulations. Because of the technical difficulties associated with testing complex mixtures, the TSCA program has traditionally focused on the toxicity of discrete chemcial substances rather than on complex mixtures such as fuels and additives. In fact, under the Premanufacturing Notification process implemented for new chemical review, TSCA excludes chemical mixtures except those which occur in nature. Moreover, under both CAA and TSCA programs, persons may submit existing data to fulfill regulatory requirements

and are not required to submit duplicative data. Nevertheless, some individual chemicals used in fuel and additive formulations have been subject to review and testing under TSCA. EPA's plan to limit the focus of section 211 regulations to emmissions-based effects will help to avoid the possibility that such activities under TSCA might overlap with testing requirements promulgated under section 211(b).

Concerns about potential regulatory overlap were also raised in conjunction with the mobile source-related air toxics provisions added by the 1990 CAA Amendments (CAA Section 202(l)). Section 202(l) requires that EPA complete a study of the need for and feasibility of controlling unregulated toxic air pollutants associated with motor vehicles and fuels. Based on this study, EPA must promulgate vehicle or fuel standards to control mobile source emissions of benzene and formaldehyde. At EPA's discretion, other toxic pollutants may also be controlled.

In the opinion of some respondents, EPA's informational objectives in regard to the air pollution effects of fuels and additives would be better served by the air toxics provisions of section 202(l) than by the health and environmental provisions of section 211(b). According to this view, section 202(l) mandates a more direct approach, focusing on specific mobile source air pollutants which represent the greatest risk to human health and requiring the identification of currently unregulated mobile source pollutants which should be subject to control.

While acknowledging that the two parts of the CAA share a general concern about the public's exposure to toxic chemicals produced by mobile sources, EPA believes that they can complement rather than duplicate or supplant one another. Section 202(l) addresses the toxic emissions themselves, while section 211(b) focuses on the components and effects of emissions generated by particular motor vehicle fuels and additives. The required study under section 202(l) may or may not identify any fuel-related causes of toxic air pollutants, while the testing required under section 211(b) will provide such information. This should prove useful in EPA decisionmaking regarding the need for feasibility of additional vehicle or fuel regulations to reduce toxic emissions. Furthermore, a different regulatory approach underlines each of the two statutes. Section 202(l) seeks to determine the extent to which existing toxicologic data on specific identified air pollutants warrants additional regulation, and requires certain EPA actions in this regard by mid-1995. The purpose of the current rulemaking is to establish testing requirements that will provide EPA with adequate information on the emissions effects of existing and future fuels and additives to determine whether the commercial distribution or use of any such fuels or additives should be controlled.

2. Emission Control System Testing

Several respondents representing segments of the vehicle and engine manufacturing industries favored rigorous requirements for testing the potential effects of fuels and fuel additives on vehicular emission control performance. These respondents maintain that emission control test requirements under this rulemaking should involve different driving cycles for urban vehicles, tractor trailers, and alternatively fueled vehicles, and should include such parameters as long-term durability, deterioration rate, wear, corrosion, deposition, and compatibility with a variety of lubricating oil formulations. Furthermore, they argued that test requirements for existing products should be just as stringent as those required for the market entry of new fuels and additives, and that the effects of each fuel or additive on emission control performance should be tested in a statistically significant sample of engines.

EPA recognizes the concerns of these respondents regarding the potential impact of fuel and/or additive formulations on emission control system integrity. On the other hand, it is not in the public interest to establish registration requirements so onerous that they would discourage the introduction of beneficial new additives and alternative fuels.

EPA believes that the existing prohibitions in section 211(f) have avoided these unfavorable results while preventing the introduction of fuels and additives which would significantly degrade the performance of emission control equipment. In effect, these mechanisms call for emission control testing of fuels and additives only when their composition departs significantly from the general range of fuel formulations which would ordinarily be anticipated by manufacturers of motor vehicle engines and emission control devices. This objective has been accomplished by the issuance of interpretive rules which lay out specific chemical and physical criteria for a category of fuels and additives considered "substantially similar" to certification gasoline fuels (46 FR 38582 and 56 FR 5352). Products which meet these "sub sim" criteria can be placed in commercial use without first undergoing testing to determine their potential emission control impact. Conversely, manufacturers of fuels and additives which do not conform to the "sub sim" criteria are required to apply for a waiver of section 211(f) restrictions. This process requires the waiver applicant to demonstrate, through testing if necessary, that such products do not decrease the ability of vehicular emission control systems to comply with emission standards.

Section 211(f) was passed by Congress in 1977, seven years after enactment of the section 211(b) provisions which are the primary subject of today's proposed rulemaking. In EPA's judgment, the mechanisms already implemented under section 211(f) are adequate to satisfy the section 211(b) requirement for testing to determine the effects of fuels and additives on emission control systems. Three factors must be considered in this regard: (1) The adequacy of test procedures conducted for the purpose of waiver applications under section 211(f), (2) the adequacy of existing "sub sim" criteria for determining which fuels and additives must apply for a section 211(f) waiver, and (3) the scope of section 211(f) prohibitions. These factors are discussed below.

(1) *Adequacy of testing.* While EPA believes that the level of emission control system testing conducted in support of section 211(f)(4) waiver requests has generally been appropriate and effective, the comments summarized at the beginning of this subsection indicate that some industry segments consider such testing inadequate for determining the potential impact of fuels and additives on emission control devices. To the extent that more comprehensive or standardized emission control test requirements might be needed, EPA believes they should be implemented as changes to the existing waiver application procedures under section 211(f) rather than as new, overlapping regulations under section 211(b). While such revisions are outside the scope of the proposed rulemaking, EPA would separately welcome suggestions regarding possible changes in conjunction with section 211(f).

(2) *Adequacy of "substantially similar" criteria.* In EPA's view, more than a decade of experience has demonstrated the practical value of the "substantially similar" concept for determining whether a fuel or additives needs to be tested for its effects on emission control equipment. Among gasoline fuels and their related bulk

additives (the only fuel/additive categories subject to section 211(f) prohibitions prior to the 1990 CAA Amendments), EPA is not aware of instances in which products excused from testing because they met "sub sim" criteria were later discovered to have adverse effects on vehicular emission control performance. Rather than tightening up the criteria, the Agency has been persuaded by practical experience in conjunction with the waiver application process to publish a revision of the "substantially similar" definition, which raised the limitation on the amount of oxygen permitted in formulations considered to be "sub sim".

(3) *Scope of section 211(f) prohibitions.* Until the 1990 CAA Amendments went into effect, the statutory language of section 211(f) was interpreted as applying only to unleaded gasoline fuels and related bulk additives. Interpretive rules establishing the criteria for fuels and additives considered to be "substantially similar" to certification fuels thus were published only for products in the unleaded gasoline category. With enactment of the 1990 CAA Amendments, all types of motor vehicle fuels and additives were placed under section 211(f) jurisdiction. Proposed criteria for fuels and additives considered "substantially similar" to diesel fuel have now been published (56 FR 24362–3, May 30, 1991). In addition, "sub sim" criteria appropriate to other fuel/additive categories are now under development or planned for all fuels (other than leaded gasoline) for which certification procedures and emission standards exist.

However, the expanded scope of section 211(f) applies only to products first introduced into commerce on or after November 15, 1990, the effective date of the CAA Amendments. Consequently, a large number of products introduced and/or registered prior to this date will still fall outside the regulatory domain of section 211(f). These "grandfathered" products include aftermarket additives sold for use in gasoline-powered vehicles, as well as all non-gasoline fuels and fuel additives, introduced prior to the 1990 CAA Amendments. If these products are to be subject to possible testing requirements and regulatory control on the basis of their potential emission control effects, the statutory authority has to derive from sections 211(b) and (c) rather than section 211(f).

The possibility that some grandfathered products may have deleterious effects on emission control performance is addressed in the proposed rulemaking as follows. In general, section 211(b) provisions relating to emission control system testing are integrated with the regulatory structure of section 211(f). Products not subject to section 211(f) because they were first introduced prior to the effective date of the applicable prohibition would not routinely be required to undergo emission control testing. However, the proposed rulemaking provides a mechanism by which EPA can choose to require testing for such grandfathered products, similar to the testing which a waiver applicant would have to conduct, if so petitioned by outside parties or if other information available to the Agency indicates that such review is appropriate. This topic is further discussed below in section III.D.

3. Grouping Provisions

The ANPRM discussed EPA's intent to develop a grouping system by which manufacturers of similar fuels and additives could voluntarily pool their efforts and resources to satisfy program requirements. According to this plan, fuels and additives would be grouped according to criteria specified by EPA. Representatives from each group would then be selected for testing, with the test results and attendant costs shared by the participating manufacturers. As a result, both costs and duplicative efforts would be reduced.

Public comment about the grouping concept was generally supportive. However, at least one respondent pointed out that participation in cooperative testing arrangements would not be a viable option for makers of proprietary specialty fuel additives, because valuable trade secrets about product formulations would have to be revealed to potential competitors. EPA acknowledges that the opportunity for group participation will be most attractive to manufacturers of generic or commodity-type products. On the other hand, there are a number of approaches under which group participation may not require detailed chemical formulations to be divulged. For example, persons could use an agent, such as an accouting firm or a trade association, to coordinate testing and represent the group to EPA while preserving the anonymity of the other members in the group. Manufacturers of specialty products will have to judge for themselves whether the amount of confidential business information that must be revealed in order to participate in group testing arrangements is acceptable to them.

In regard to the development of criteria for establishing the groups, a number of respondents suggested that fuels and fuel additives be grouped according to their emission components. EPA agrees that emissions-based grouping would be ideal, but until this rulemaking has gone into effect, the requisite information on emission will not be available. Recognizing this problem, some respondents suggested that EPA first collect emissions data from fuel and additive manufacturers and then develop the grouping criteria. However, to follow this suggestion would necessitate two separate regulatory proceedings: A preliminary rule requiring manufacturers to submit the results of emission speciation procedures and a second rule creating an emissions-based grouping system and promulgating regulations to implement all of the other program requirements. This is not a viable alternative for the Agency, given the time constraints of the statute and the provisions of the Consent Decree. Therefore, the grouping system proposed here is based on the composition of raw fuels and additives, with the underlying assumption that fuels and additives with similar raw constituents will generate similar emissions.

Some respondents submitted specific suggestions to EPA concerning the definition of fuel and additive groups. For example, one respondent proposed that fuels be subdivided for health testing on the basis of their octane number and/or PONA number (paraffins, olefins, naphthenes, and aromatics). EPA has not found these numerical indexes useful for distinguishing meaningful health effects testing groups. Moreover, the significance of the associated hydrocarbon proportions in the raw fuel state will be reduced in the case of the exhaust emission by the "homogenizing" effect of the combustion process. Nevertheless, recent evidence suggests that varying the relative olefin and/or aromatic content of a fuel may impact the concentration of some emission components. Thus, olefin and aromatic content are among the parameters under consideration by EPA for defining groups or selecting group representatives for testing.

Opinions differed among respondents about the usefulness of the section 211(f) "substantially similar" criteria in the context of a grouping system for fuel and additive health testing. As previously described, the "sub sim" criteria currently serve to designate which fuels and fuel additives must obtain a waiver of section 211(f) prohibitions. While some respondents endorsed the incorporation of existing "sub sim" criteria into the grouping

system for health effects testing, others felt that the resulting "sub sim" group would be too broad to allow the health test results obtained for selected representatives to be generalized to the group as a whole.

EPA believes that, in most respects, the "sub sim" criteria (56 FR 5352, February 11, 1991) are useful determinants of "baseline" conventional fuels and fuel additives (see section IV of this NPRM). The established criteria restrict the elemental composition of "sub sim" formulations to carbon, hydrogen, oxygen, nitrogen, and sulfur, with limits placed on the amount of methanol, oxygen, sulfur, and certain other substances. However, EPA is considering several variants of these criteria for distinguishing between "baseline" and "non-baseline" formulations. Extreme concentrations of aromatics and olefins are two possible distinguishing characteristics. A different restriction on the amount of oxygen permitted in baseline formulations is another possibility. The oxygen restriction for "sub sim" fuels is currently 2.7 percent by weight (and somewhat higher for certain waivered fuels and additives), and this may be appropriate for defining baseline formulations in this proposed program. However, EPA is also considering restricting baseline formulations to those with less than 1.5 weight percent of oxygen. In the latter case, "reformulated" fuels would be excluded from the "baseline" classification. This would result in the generation of more explicit information for various oxygenated gasoline fuels.

4. Health Effects Testing Provisions

A number or respondents argued that an overly stringent and expensive health effects testing program would be counter to the public interest. They pointed out that unreasonably high costs of program compliance would discourage the development of new fuels and additives and would reduce the availability of products potentially beneficial to the public health and welfare. While the testing program must provide adequate information for assessing the toxicity of fuels and additives, EPA is well aware of the importance of striking an appropriate balance between scientific demands and technical and financial constraints, taking into account both the need for adequate information and the need for continued innovation. The Agency believes that the program outlined in the proposed rulemaking is consistent with the statute and reflects a reasonable and cost-conscious approach to a very complex regulatory area.

In comments directed at the health assessment approaches described in the ANPRM, respondents urged EPA to include provisions for taking relevant existing information into account, to use a tiered testing approach as a means for identifying products which should undergo long-term study, and to take advantage of existing standardized test guidelines whenever possible. These suggestions are reflected in today's proposed rule.

Some respondents stated that successful implementation of a broadly-based health effects testing program was doubtful in view of the many technical problems which must first be overcome. They maintained that years of testing would be required to validate test protocols and establish baseline data, in view of the chemical complexity of fuel and additive formulations and the impact of vehicle choice, engine type, emission control technology, and operating conditions on the composition of emissions.

EPA is well aware of these technical difficulties, but does not agree that they are insurmountable. Today's proposed rule contains a number of proposals for bringing the sources of variability under reasonable control, including rules for the selection and operation of vehicles and equipment, base fuel specifications for each major fuel/additive family, standardized procedures for the generation, sampling, and storage of emissions, and guidelines for animal inhalation exposure testing. Together with experimental control requirements, these measures should reduce the testing program's inherent variability to acceptable limits. EPA invites comments from the public on the adequacy of these measures and on ways to improve them.

Many commenters urged EPA to "set priorities" for testing among the large universe of motor vehicle fuels and fuel additives potentially subject to the proposed rulemaking. However, there was little agreement about which specific formulations or product categories—fuels vs. additives, conventional vs. reformulated vs. alternative fuels—should be placed high and low on the priority list. Under section 211, Congress has mandated that EPA enact a scheme for testing that would generally and reasonably assess the health risks of all fuels and fuel additives. Therefore, EPA has proposed a grouping system which provides an efficient mechanism for obtaining information on all types of fuels and additives. A system of evaluation tiers has also been developed, enabling EPA to determine whether more definitive testing is needed for any particular fuels or additives (or types of fuels and additives) based upon toxicity and exposure data obtained from the literature, from modeling techniques, and from a battery of screening tests. Finally, EPA intends, under section 211(e)(3)(C), to recognize existing adequate data as compliance with the rule.

Related comments were submitted regarding the applicability of program requirements to fuel additives which are considered "substantially similar" to conventional fuels. Some respondents pointed out that when a "sub sim" additive is mixed with gasoline it is extremely difficult if not impossible to differentiate from the fuel itself, and that efforts to detect the negligible contribution of such an additive to the emissions produced by the gasoline/additive mixture would be futile. Thus, according to these respondents, "sub sim" fuel additives should be exempt from program requirements.

EPA agrees with some of the reasoning behind these arguments. The public health and welfare provisions in this rulemaking are concerned with the impact of emissions generated by fuels and fuel additives in normal use. Since additives are properly used only in conjunction with their associated fuels, program requirements pertaining to the potential effects of additives are focused specifically on the emissions of the respective fuel/additive mixtures. For additives with essentially the same chemical makeup as their parent fuels, currently available technology will generally not be capable of differentiating the emission products of the additive/fuel mixture from the emission products of the parent fuel itself.

EPA does not agree, however, that the manufacturer of an additive should be relieved of registration responsibilities just because of the additive's similarity to its parent fuel. Instead, provisions within the proposed grouping system should be able to account for these relationships. Such mechanisms are discussed further in section IV, below.

5. Small Business Provisions

Under section 211(e), EPA is authorized to create special program allowances and/or exemptions which would reduce the burdens of program compliance for small businesses. If EPA should choose to exercise this authority, the operative definition of a small business would be specified within the associated regulations. Respondents who commented on this matter felt that any small business definition would be arbitrary and unfair. In their view, small

business provisions could potentially place individual manufacturers who sold multiple low-volume products at a disadvantage relative to single-product manufacturers. They also believed that the rules governing small business allowances could be manipulated by large manufacturers, creating loopholes never intended by EPA.

While EPA does not necessarily share each of the respondents' concerns, this NPRM does not contain specific proposed provisions for small businesses. In general, the proposed grouping scheme, tiered testing structure, and other general provisions should assure that undue burdens are not placed upon small businesses. Nevertheless, EPA's analysis indicates that the costs of compliance with the proposed program may place a few small businesses in financial jeopardy. EPA is thus attempting to identify the characteristics which may make some small companies unusually vulnerable to the potential financial impact of the proposed requirements, and to specify fair and appropriate approaches for providing cost relief to such companies. These topics are discussed further in section VIII.C.

E. Key Terms

A *fuel* is defined to be any material which is capable of releasing energy or power by combustion or other chemical or physical reaction. Only fuels intended for use in motor vehicles are included under the proposed regulations. Currently, fuels intended for use exclusively in off-road vehicles are not designated for registration. Both domestic and foreign products are included in the designation.

A *fuel additive* is any substance that is intentionally added to a fuel and that is not intentionally removed prior to sale or use. *Bulk additives* are products which are added to fuel before the fuel is commercially available for introduction into the fuel tank of a motor vehicle, whether added at the refinery as part of the original blending stream or after the fuel is transported from the refinery. *Aftermarket additives* are products marketed for introduction directly into the fuel system of a motor vehicle.

A *base fuel* is a generic fuel formulated from a set of specifications to represent a given fuel family and used in conjunction with the testing of additives in that family.

Combustion emissions are the exhaust products of the combustion of fuel and/or additives in a motor vehicle engine. For the purposes of this rulemaking, this designation refers to controlled exhaust products (i.e., post-aftertreatment tailpipe emissions) unless otherwise specified.

Evaporative emissions are chemical compounds emitted into the atmosphere by vaporization of the components of a fuel or additive/fuel mixture. For purposes of this rulemaking, the term "evaporative emissions" refers both to emissions created by vaporization from the fuel system of a motor vehicle (hot soak, diurnal, and running losses) as well as those displaced from the fuel tank by incoming fuel during refueling operations.

Atmospheric transformation products are compounds formed in the atmosphere from the reactions of primary emissions such as volatile organic compounds (VOCs) in the presence of atmospheric gases such as nitrogen oxides. The formation of many such compounds also requires the presence of sunlight. Transformation products include ozone, formaldehyde, peroxylacetyl nitrate (PAN), and other nitrated and oxygenated low molecular weight organic compounds.

III. Program Scope

A. Overall Purpose and Applicability

Section 211 of the Clean Air Act establishes a framework for registering motor vehicle fuels and additives, for gathering information about them, and for possibly limiting or prohibiting their commercial distribution and sale when the available information warrants such action. Previous regulatory actions have implemented sections 211 (a) and (b)(1), which govern the general registration of fuels and additives, as well as section 211(f), which prohibits the commercial introduction of certain fuels and additives prior to a demonstration by the prospective registrants that these products do not adversely affect emission control system performance. Today's Notice proposes new registration requirements for motor vehicle fuels and fuel additives under sections 211 (b)(2) and (e). These sections grant EPA authority to require information on the potential health, welfare, and emission control system effects associated with motor vehicle fuels and additives, and to specify procedures and protocols to be used by fuel and additive producers in complying with these requirements.

The proposed new requirements would apply to any motor vehicle fuel or additive which is already registered or is subject to the general registration requirements in effect under sections 211(a) and 211(b)(1). At the present time, this designation encompasses both current and new gasoline and diesel fuels and additives produced and commercially distributed for use in motor vehicles. While alternative fuels and their additives are not yet designated for registration, EPA plans to designate them before this proposed rule becomes final. Currently, fuels and fuel additives intended only for off-road vehicular use (e.g., in farm and construction equipment, aircraft, boats, and railroad engines) do not need to be registered, and thus are not subject to the new registration requirements proposed in this rulemaking. However, if these fuels and additives are covered under future registration requirements, this program (modified as needed) would extend to them as well.

By this proposed rule, EPA intends to satisfy Congress' mandate under section 211(e) that EPA implement its authority under section 211(b). EPA interprets section 211(b) to give it the authority to require testing of fuels and fuel additives to identify their health and environmental effects. Section 211(b), however, must be read in conjunction with section 211(c), which in part gives EPA authority to control or prohibit the manufacture, introduction into commerce, offering for sale, or sale of any fuel or fuel additive if the Administrator finds that the emission products of such fuel or fuel additive "causes, or contributes, to air pollution which may reasonably be anticipated to endanger the public health or welfare." Further, the Administrator must find that such prohibitions "will not cause the use of any other fuel or fuel additive which will produce emissions which will endanger the public health or welfare to the same or greater degree than the use of the fuel or fuel additive proposed to be prohibited." Therefore, the purpose of section 211 is not to require submission of data and information for its own sake, but to assist EPA in the regulation of fuels and fuel additives.

EPA faces practical constraints in accomplishing its task. Currently, 2,200 fuels and 4,100 fuel additives are registered for use. Emissions speciation and emissions toxicity testing are complex, requiring the operation of vehicles or engines in a laboratory and, in the case of toxicity testing, the inhalation exposure of animals to emissions under very controlled conditions. EPA knows of only a few commercial laboratories which currently offer the full range of emission generation and speciation procedures proposed in this rule, and is not aware of any commercial biological testing facilities which, at the present time, offer toxicity testing services involving the constant inhalation exposure of live animals to fuel and fuel additive

emissions. Also, while screening batteries can be conducted in only a few weeks or months, more extensive testing may require long term exposures or the exposure of more than one generation of animals.

Accordingly, the proposal attempts to address these practical constraints while providing EPA with sufficient information to exercise its authority under section 211(c). First, EPA proposes to recognize adequate existing data. By adequate, EPA would recognize studies conducted reasonably in accord with the guidelines specified in this rule. Second, EPA has proposed a voluntary grouping scheme by which manufacturers of fuels and fuel additives with similar chemical composition may test one substance as a representative of all substances within the group. (Because manufacturers may not wish to share data on the composition of their products with others, the grouping scheme would be voluntary; however, each fuel or fuel additive would be required to be tested either separately or as part of a group.) EPA would use the information from the test substance to evaluate the risk of all substances within the group, unless adequate data on a particular member of the group becomes available. Manufacturers would benefit by sharing the cost of testing. Through this voluntary grouping system, EPA estimates that, among currently registered unleaded gasoline, leaded gasoline, and diesel products, about 115 groups could be formed, which is a much more reasonable number of testing subjects given the practical constraints on testing. Test data obtained as a result of the proposed rule would thus give EPA a general picture of how different types of fuels and fuel additives compare to one another, which is consistent with section 211(b) in light of EPA's authority under section 211(c).

Fuels and additives registered as relabeled products (i.e., simply repackaged versions of formulations which are also registered by the original manufacturers) would be specifically exempted from the new information gathering and testing requirements proposed in today's rulemaking. Because separate assessment of relabeled products would clearly duplicate the efforts of the original manufacturer, EPA has chosen to exercise the authority in section 211(e)(3)(C), which allows EPA to exempt fuels and additives from the provisions of section 211(b)(2) under duplicative circumstances. However, if the original manufacturer should fail to fulfill the proposed registration requirements, then the relabeler would be at risk for losing his supply of the relabeled product. Furthermore, EPA expects that the original manufacturers would pass the costs of testing along to their customers, including repackagers.

In another matter pursuant to section 211(e)(3)(C), EPA requests comment from the public in regard to the adequacy of existing information on "baseline" conventional fuels and fuel additives, including baseline diesel, unleaded gasoline, and leaded gasoline formulations (as defined in Section IV, below). A multitude of studies, conducted by many researchers over several decades, have addressed the emissions-based effects of these products on the public health and welfare and on emission control system performance. The published results and conclusions from these tests have provided the foundation for many legislative initiatives and regulatory actions in the area of mobile-source air pollution. EPA invites detailed comment on the extent to which the available information on these conventional fuels and additives is adequate for ongoing regulatory decision-making and, with respect to the testing requirements proposed in this rulemaking, the extent to which significant gaps may still remain in the available data base.

B. Emissions Focus

While the requirements proposed in this NPRM are primarily concerned with information collection, the underlying purpose of the rule is to guide the direction of related regulatory activities which might be undertaken in the future. The statute instructs EPA to promulgate requirements for "reasonable and necessary" information about the effects of fuels and additives and, as described above, provides mechanisms under section 211(c) for taking action based upon this information. Therefore, it would appear most reasonable in this instance for EPA to focus its information requirements to subject areas which serve the regulatory objectives of section 211(c).

Accordingly, EPA interprets section 211 to give it authority to focus testing on the emissions effects of fuels and fuel additives. By emissions effects, EPA means both the effects from combustion and evaporation of fuels and fuel additives resulting from their use in motor vehicles. The purpose of obtaining data on fuels and fuel additives is to provide a basis for further risk characterization and possible regulation under section 211(c). CAA section 211(c)(1) states:

> The Administrator may, from time to time on the basis of information obtained under subsection (b) of this section or other information available to him, by regulation, control or prohibit the manufacture, introduction into commerce, offering for sale, or sale of any fuel or fuel additive for use in a motor vehicle * * * (A) if in the judgment of the Administrator any emissions product of such fuel or fuel additive causes or contributes to air pollution which may reasonably be anticipated to endanger the public health or welfare * * * or (B) if emission products * * * will impair * * * the performance of any emission control device or system in general use * * *

Similarly, CAA section 211(c)(2)(C) states:

> No fuel or fuel additive may be prohibited by the Administrator under paragraph (1) unless he finds, and publishes such finding, that in his judgment such prohibition will not cause the use of any other fuel or fuel additive which will produce emissions which will endanger the public health or welfare to the same or greater degree than the use of the fuel or fuel additive proposed to be prohibited.

Thus, the plain language of CAA section 211(c) states that EPA is authorized to regulate fuels or fuel additives based on the impact of their emissions on health or welfare. This is consistent with the legislative history of the provision as well. The House and Senate Reports on the CAA Amendments of 1970 link the information to be obtained under CAA section 211(b) to EPA's authority to regulate under CAA section 211(c).[1] The Senate explicitly stated:

> In matters related to public health and welfare, the Committee's concern is with the effect of the actual emissions from the tailpipe, not with the composition of the fuel. The combustion of the fuel in its intended environment—inside an engine with emission control would be the proper criterion for the Secretary to use in judging the health and welfare effects of that fuel. (Leg. Hist. at 434)

The legislative history of the 1977 CAA Amendments also indicates that CAA section 211 is focused on emissions effects. For example, in characterizing section 211(b), the House report states that it allows testing "to determine the health effects of the emission products of fuels or fuel additives." [2] Thus, based on the plain language of the statute and its legislative history, EPA believes it is reasonable to interpret section 211 of the Clean Air Act to allow EPA to focus testing on the emissions effects of fuels and fuel additives.

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[1] H. Rep. No. 1146, 91 Cong. 2d Sess. (1980) at 13, reprinted in Environment and Natural Resources Division of the Library of Congress, 93d Cong., 2d Sess.: A Legislative History of the Clean Air Act Amendments of 1970 (Comm. Print 1974) ("Leg. Hist.") at 433–434.

[2] N. Rep. No. 294, 95th Cong., 1st Sess. (1977) at 25, reprinted in 1977 U.S. Code Cong. & Ad. News 1103.

The proposed emissions focus will help to avoid overlap with regulatory initiatives which may be taken in conjunction with the Toxic Substances Control Act (TSCA), the Resource Conservation and Recovery Act (RCRA), and the Occupational Safety and Health Act (OSHA). Under certain circumstances, the health and/or welfare effects associated with the production, handling, and use of fuels and additives may fall within the domain of these other regulatory programs. Restricting the general focus of today's proposed rulemaking to the effects of fuel and additive emissions will help to minimize the potential for programmatic overlap.

C. Applicability of Types of Emissions

Both combustion emissions (exhaust) and evaporative emissions are major contributors to potentially harmful air pollution, and both are included within the general focus of today's proposed rule. Concerns about the public health impacts of emissions from both of these sources are documented in the legislative proceedings associated with the enactment of section 211. Since that time, however, a number of existing and planned regulatory initiatives and industry innovations have decreased the potential risk of exposure to fuel and additive evaporative emissions, including the vapors which arise from fueled vehicles and those which are released during refueling operations. Thus, EPA invites comments in regard to the continuing need for assessing the health and environmental effects of evaporative emissions.

Exhaust emissions are inevitable products of the engine combustion process, and requirements to assess the potential adverse effects of engine exhaust are generally applicable to all motor vehicle fuels and fuel additives. This is not always true for evaporative emissions. In the case of fuels which are supplied to motor vehicle engines by way of sealed containment and delivery systems (e.g., liquified petroleum gas and compressed natural gas), the need for evaporative emission testing is less important, since human and ecosystem exposures will be extremely low or nonexistent. For ordinary liquid fuels and additives, the significance of vaporization varies widely, depending on the inherent volatility of the fuel or additive.

In this regard, a readily available volatility measurement which correlates with fuel tank evaporative losses is the Reid Vapor Pressure (RVP). Based on empirical analysis, EPA proposes that an RVP of 2.0 pounds per square inch (psi) be designated as the threshold for determining the applicability of evaporative emission testing requirements for fuels. That is, fuels with RVP of 2.0 psi or greater would be subject to information and testing requirements established for evaporative emissions, while those with RVP less than 2.0 psi would be excused. Among motor vehicle fuels available in today's marketplace, only diesel fuel, with its extremely low volatility reflected in an RVP of approximatley 0.1 psi, falls below the proposed threshold. Gasoline, alcohol fuels, and gasoline/oxygenate blends have RVPs well above the 2.0 psi cutoff point, and would thus be subject to any requirements which might be established for evaporative emission testing. Arguments can be made that other RVP cutoff points in the range of 2.0–5.0 psi might also be appropriate, and EPA requests comments on the best alternative.

With respect to additives, EPA proposes to require evaporative emission testing when the applicable additive/base fuel mixture meets either of two criteria. First, evaporative emission testing would be required if the RVP of the additive/base fuel mixture is increased by 0.1 psi or more in comparison with the RVP of the base fuel alone. Second, evaporative emission testing would be required if the partial pressure of the additive in the vapor phase, at 100 degrees Fahrenheit and atmospheric pressure, is 0.1 psi or greater. The partial pressure of the vaporized products of the additive/fuel mixture in ambient air could be determined through testing or by using thermodynamic models that account for the vapor pressures and interactions of the substances involved. While the specified criteria reflect a conservative approach, they would not require testing when an additive has a negligible volatility effect.

EPA asks for comment in regard to the suitability of using Reid Vapor Pressure and partial pressure measurements to determine the applicability of evaporative emission testing requirements for fuels and additives. Comments are also invited regarding the proposed threshold RVP and partial pressure values.

In addition to requirements for testing the effects of combustion and evaporative emissions, EPA has considered incorporating the atmospheric transformation products of such emissions within the proposed testing program. Transformation products arise in the atmosphere from a series of extremely complex chemical reactions involving atmospheric gases and volatile emissions, usually in the presence of ultraviolet sunlight. One of the results of the transformation process is known as photochemical smog. Its characteristics include reduced visibility, high levels of oxidants such as ozone, formaldehyde, acrolein, peroxyacetyl nitrates, and other oxygenated and nitrated organic substances. These secondary air pollutants from motor vehicle emissions are prevalent in the air of all urban areas in the United States, posing threats to public health, vegetation, and materials which may surpass those associated with the parent compounds themselves. By causing crop losses and accelerating the deterioration of natural and man-made materials such as rubber, paint, building stone, and fabric, urban smog also causes substantial economic losses. Thus, atmospheric transformation products are a major factor to be considered in characterizing the overall risks associated with fuel and additive emissions, and a great deal of study on their formation and effects is needed.

At the present time, however, rather than requiring laboratory testing of transformation products, EPA is proposing a theoretical approach to the issue. The conduct of valid sampling and testing procedures on the primary emissions of fuels and additives requires many technical problems to be overcome and many sources of variability to be addressed. These complexities are compounded further when attempting to create secondary transformation products of the emissions under controlled conditions and trying to carry out a meaningful testing program on the resulting chemical mixture.

While the scientific community has begun to develop experimental methods for modeling emission transformation processes in the laboratory, experience in this area is relatively limited and the necessary facilities are available in only a very few academic settings. Furthermore, the current knowledge base in this field of investigation does not permit the unequivocal identification of cause and effect relationships between discrete fuel or additive formulations and specific products of photochemical transformation. Thus, even if a broad-based testing program could be implemented, the results would probably not be useful in discriminating the specific contributions of different fuels and additives to the formation and effects of transformation products.

These scientific, technical, and practical considerations have persuaded EPA to exclude laboratory testing requirements for atmospheric

transformation products from today's proposed rule. However, these considerations do not preclude theoretical approaches for providing information about the photochemical reactivity of the emission products of fuels and fuel additives. Possible approaches include the use of mechanistic kinetic models, which can in many instances predict the degradation products arising from atmospheric photochemical reactions, or theoretical projections by qualified atmospheric chemists. Such requirements are included in the proposed program and are discussed further in Section VI.B of this NPRM. Furthermore, requirements for direct laboratory testing of atmospheric transformation processes may be added in future amendments to the rule if advances in the field make this feasible.

D. Scope of Emission Control System Testing

As previously discussed (see section II.D.2), EPA proposes to satisfy the provisions in section 211(b)(2) regarding emission control system testing by reference to the existing fuel and additive waiver application program implemented under section 211(f). Under the existing program, fuel and additive formulations which are not "substantially similar" to designated certification fuels (as defined in 56 FR 5352, February 19, 1991) cannot be introduced into commerce unless a waiver is issued by EPA. To obtain such a waiver, the producer of the fuel or additive must show that the "dissimilar" product does not adversely affect the ability of a motor vehicle's emission control system to achieve compliance with certification standards during the useful life of the vehicle.

A waiver request must address the impact of the product on tailpipe emissions, evaporative emissions, materials compatibility, and driveability. This has typically involved emission testing in accordance with the Federal Test Procedure (FTP) (40 CFR part 86) and, in certain cases, substantial durability testing to assess potential long-term effects.

Rigorous protocols are necessary to ensure fully that emission control performance will not be compromised, and are warranted for fuels or fuel additives which depart from conventional formulations. As routine requirements for the registration of fuels and additives, however, such rigorous and costly protocols may not be reasonable. The section 211(f) waiver program functions on an exception basis, an approach which has proven both practical and effective as applied to unleaded gasoline fuels and additives. Revisions currently under development will extend the applicability of the waiver program to other fuel and additive categories for which emission certification standards are established. These changes will enhance the capacity of the waiver program to adequately fulfill the aims of the emission control testing provisions of section 211(b).

Therefore, the emission control system testing provisions in today's proposed rulemaking are fully integrated with the existing section 211(f) program. With respect to new fuels and additives, manufacturers' responsibilities in this area would be unchanged. Products which conform to applicable "sub sim" definitions would not be required to undergo emission control system testing before they can be registered. On the other hand, new fuels and additives which do not meet "sub sim" criteria would be subject to the regular section 211(f) waiver application process prior to registration.

The only proposed new application of EPA's authority under section 211(b) to require emission control testing pertains to fuels and additives which were registered in the past even though they were not "sub sim" and did not undergo waiver application procedures. As discussed previously in section II.D.2 of this NPRM, such registrations have occurred because fuel and additive products other than unleaded gasoline and related bulk additives did not become subject to section 211(f) prohibitions until the enactment of the CAA Amendments on November 15, 1990. As a result, some "non-sub-sim" products introduced prior to that date were allowed to be registered without first undergoing the emission control system testing which the waiver application process ordinarily entails. Nevertheless, in the absence of evidence linking "grandfathered" products to emission control system problems, EPA believes it may not be reasonable or necessary to force all such products to undergo emission control system testing years after their initial registration and commercial distribution.

Such evidence of adverse emission control effects may come to light as a result of emission characterization requirements included within the health effects testing provisions of today's proposed rulemaking. The proposed emission characterization requirements include Federal testing procedures to determine the levels of regulated emissions generated by the fuel/additive of interest. Should any of the regulated emission products exceed established certification standards, a need for examination of the product's effects on emission control may be indicated.

EPA also proposes to set up a mechanism which would permit vehicle manufacturers or other outside parties to submit petitions to EPA, citing evidence that certain brands, formulations, or specific components of fuels or additives are harmful to vehicular emission control. If EPA judges that emission control system testing is warranted after reviewing the petition arguments, emission characterization results, and/or other available information, the authority provided by section 211(b) will be exercised to bring specified fuels and additives into the waiver application program when they would otherwise be excused by the "grandfathering" provisions of section 211(f).

EPA requests comments on the adequacy of this proposed approach. As an alternative, the authority of section 211(b) could be exercised to require all "grandfathered" products to undergo waiver request procedures under section 211(f) if they do not conform to applicable "sub sim" criteria. Comments are solicited in regard to the specific necessity and the likely costs and benefits of this more comprehensive approach in comparison to the mechanism described above.

E. Scope of Health Effects Evaluation

1. Background

Registration requirements concerning the health effects of fuels and fuel additives could potentially encompass a vast range of endpoints, exposure scenarios, mechanisms of action, and experimental protocols. Taking into account the number of fuels and additives in question, a comprehensive toxicologic program could easily overwhelm the capacity of existing laboratory facilities and support systems, and the total costs of such a program would be very likely to exceed its expected benefits. Over 6,000 fuels and additives are currently registered, and this population is expected to undergo further growth in the near future as reformulated and alternative fuels and their additives gain a wider role in the marketplace.

Other than stipulating three endpoints which must, at a minimum, be included in the regulations, section 211(b) gives EPA discretion to apply its expertise in determining the scope of the health effects evaluation program. In exercising this discretionary authority, EPA has recognized that some areas of inquiry

which are of legitimate scientific interest may not be reasonable or necessary to include in the context of a regulatory program. Rather than mandating comprehensive health effects testing as a routine registration requirement for every fuel and fuel additive, the program is designed to address testing needs on a tiered basis, with allowance for more rigorous, resource-intensive requirements as indicated by existing data and lower tier screening tests.

As previously discussed, EPA's plan to focus the rulemaking on the primary emissions of fuels and additives represents a major reduction in the potential scope of the health effects evaluation program. Consistent with this focus, the proposed health testing requirements are concerned with the effects of inhalation exposure to the evaporation and combustion products of fuels and additives. They do not specifically address the possible adverse effects of exposure to fuels and additives in the liquid state, nor do they include studies of atmospheric transformation products except at the level of data analysis and modeling. Significant reductions in program costs and overall impact on the fuel and additive industry are also expected as a result of proposed grouping mechanisms and provisions for exempting relabeled products from program requirements.

2. Health Effects Endpoints

According to section 211(b)(2)(A), the endpoints to be addressed by the program must include, but need not be limited to, "carcinogenicity, mutagenicity, and teratogenicity". Carcinogencity refers to the potential of a substance to initiate or contribute to the transformation of normal cells into neoplastic cells and the further development of neoplastic cells into tumors. Mutagenicity is the ability of an agent to produce mutations, i.e., changes in the genetic information stored in the DNA of living cells. When such genetic changes occur in germinal tissue, they may represent heritable events. Teratogenicity, in the strictest sense, refers to the potential of a substance to cause adverse effects to a fetus in-utero, resulting in fetal mortality or birth defects. In today's proposed rule, EPA has chosen to expand this category to encompass general reproductive toxicity, including adult fertility effects.

In addition to these mandatory areas of inquiry, many other health effect endpoints are germane to the assessment of the public health impacts of fuel and additive emissions. As discussed further below, the proposed program incorporates a literature search which covers all such endpoints and, on a case-by-case basis, also provides for possible testing to follow up on any significant concerns highlighted by the available literature. However, testing will routinely be required for only two health effect endpoints in addition to the mandatory endpoints described above. First, consistent with the program's focus on inhalation exposure, testing of publmonary toxicity is proposed. Second, in view of particular scientific concerns about the potential effects of fuel and additive emissions on the nervous system, testing for neurotoxicity is included. Neurotoxicity also serves as a good general indicator of potentially harmful chemical activity.

3. Health Effects Evaluation Tiers

As depicted in Figure 1, the proposed requirements for evaluating the health effects of fuels and additives are organized within a three-tier structure, with more rigorous requirements contained in each successive tier. In part, each tier is intended to function as a screen for determining the need for and applicability of requirements in subsequent tiers. The tiered approach also permits fuel and additive producers to make full use of test results and other information which may already be available about their products. This is consistent with the objectives of section 211(e)(3), which authorizes EPA to take existing information into account to avoid duplicative testing requirements.

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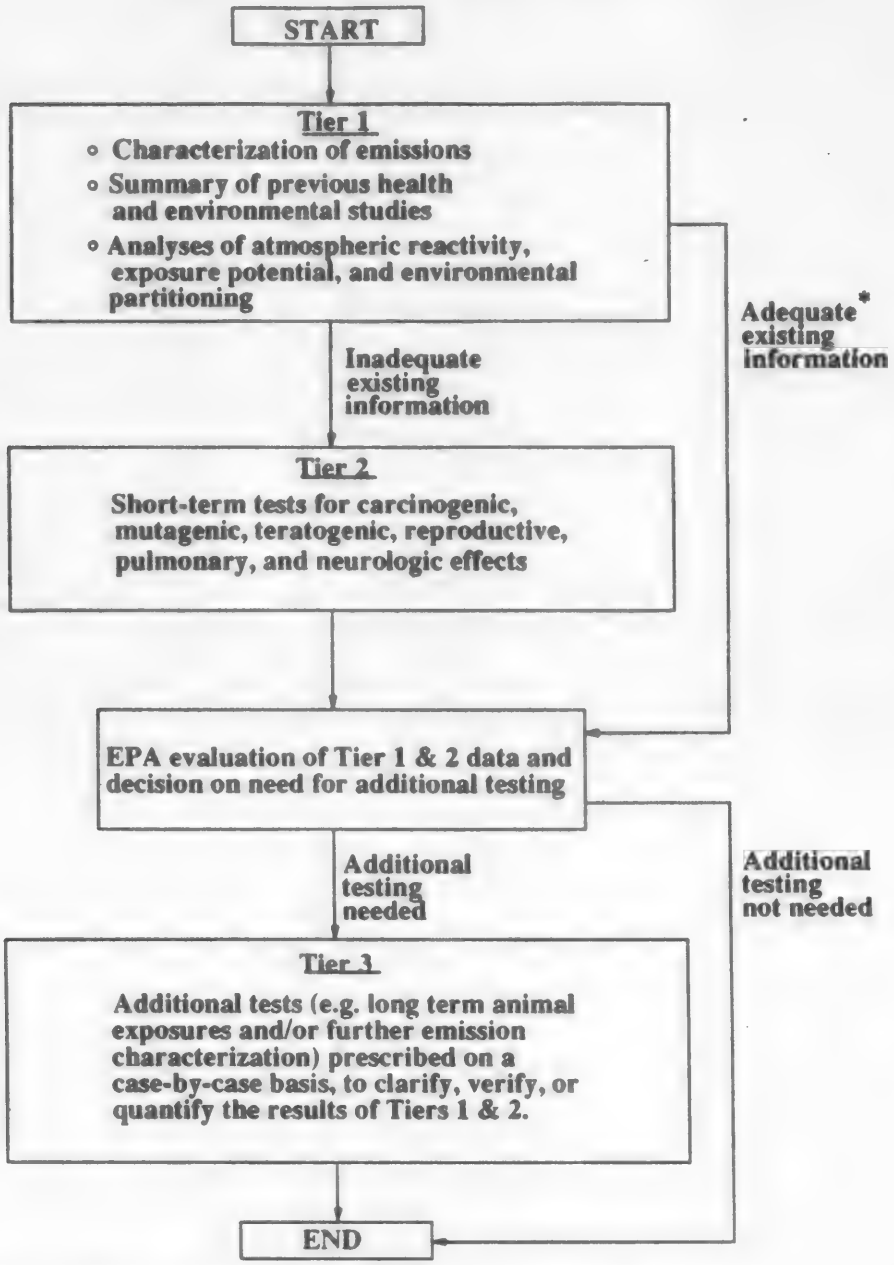
Figure 1 : Overview of Evaluation Tiers


START
Tier 1
Characterization of emissions
Summary of previous health and environmental studies
Analyses of atmospheric reactivity, exposure potential, and environmental partitioning
Adequate* existing information
Inadequate existing information
Tier 2
Short-term tests for carcinogenic, mutagenic, teratogenic, reproductive, pulmonary, and neurologic effects
EPA evaluation of Tier 1 & 2 data and decision on need for additional testing
Additional testing needed
Additional testing not needed
Tier 3
Additional tests (e.g. long term animal exposures and/or further emission characterization) prescribed on a case-by-case basis, to clarify, verify, or quantify the results of Tiers 1 & 2.
END

* "Adequate" implies that the existing information includes the results of properly performed and well-documented studies comparable to the tests required in Tier 2.

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In brief, the proposed relationship between the three evaluation tiers would function as follows. Each manufacturer of a fuel or additive would be responsible for satisfying the requirements of Tiers 1 and 2. The results of both of these tiers would be reported to EPA simultaneously, according to the report format described in section VII of this NPRM. To the extent that previously conducted studies were available for the fuel or additive which satisfied the specified guidelines for the chemical and/or biological tests required in Tiers 1 and 2, the manufacturer could submit such existing studies in lieu of performing new duplicative tests. The requirements of Tiers 1 and 2 could be satisfied by manufacturers either on an individual basis or by way of a group submission consistent with the provisions of the grouping system discussed in section IV.

Within eighteen months after receipt of a report for Tiers 1 and 2, EPA would determine whether the submitted information and testing were, in fact, in compliance with the specified guidelines. Manufacturers of existing products who failed to submit data or submitted data from tests that did not comply with the specified guidelines would be in violation of this rule and would be subject to the penalties specified in CAA section 211(d). Such persons would also have to submit the data originally required. Furthermore, if EPA determined that the data requirements of the rule were not met, EPA could revoke the registration of the subject fuel or additive. Manufacturers of fuels and additives not previously registered would be prohibited from registering and selling such products until EPA determined that the requirements of Tiers 1 and 2 were met satisfactorily.

On the basis of the submitted Tier 1 and Tier 2 data and any other available information, EPA would also determine, within five years of its receipt of a given Tier 1 and 2 submittal, whether further testing of the subject fuel or additive were required under the provisions of Tier 3. As discussed further below, this determination would depend on the extent to which Tiers 1 and 2 provide sufficient toxicity and exposure information to permit regulatory decisions to be made based on the severity and extent of adverse health risks. If Tier 3 testing were deemed necessary, EPA would notify the responsible manufacturer (or group) by certified letter of the specific Tier 3 requirement(s) along with a schedule for compliance and a deadline for submittal of the final report to EPA. EPA would provide the responsible manufacturer (or group) a 30-day comment period on the Tier 3 requirements, compliance schedule, and submission deadline. EPA would extend the comment period if it appeared from the nature of the issues raised that further time for comment were warranted. In the event that EPA received no comment within the given period, the manufacturer would be considered to have consented in full to the requirements.

To keep the general public informed about the status of the testing program and to provide an opportunity for public input to the Tier 3 decision process, EPA intends to implement additional notification procedures. Beginning three years after promulgation of the final rule, and updated at least every two years thereafter while program activity remains high, EPA proposes to publish a notice in the **Federal Register** containing the following three lists: (1) Products (or groups) for which EPA has prescribed Tier 3 testing, (2) products (or groups) for which EPA intends not to prescribe Tier 3 tests based on current information, and (3) products (or groups) for which an adequate Tier 1 and 2 submittal has been received by EPA but for which a decision on the necessity of Tier 3 testing is still pending. A product would not be included in the notice until EPA has received the respective Tier 1 and 2 submittal and has reviewed it for adequate compliance with Tier 1 and 2 requirements.

For six months following each **Federal Register** notice, EPA would accept petitions from the public requesting that particular products be required to undergo Tier 3 testing when EPA has indicated that such testing would not be prescribed or when the Tier 3 decision is still pending. To be considered by EPA, such petitions would be expected to include substantive reasons for the specific testing requested. The petitions would not be binding on EPA; however, each such petition and EPA's formal response would be placed in the docket for public inspection.

The following sections discuss the general scope of the requirements in each health effects evaluation tier and the criteria to be used in making the compliance determinations mentioned above. More detailed discussion of the individual tier requirements is provided in sections V–VII of this NPRM.

Tier 1. The scope of Tier 1 encompasses chemical analysis, literature search, and modeling or analytic methods. These components of the evaluation are designed to provide basic data on fuel and additive emission products and to permit a review and assessment of the adequacy of existing information on related health effects.

Proposed requirements for the chemical analysis of fuel and additive emissions would satisfy the provision in section 211(b)(2) "to determine the emissions resulting from the use of the fuel or additive contained in such fuel", and would also provide a useful inventory of potentially harmful fuel and additive emission products. To this end, manufacturers would be responsible for the generation, collection, and sampling of the combustion emissions of their fuels and additives, and for the conduct of tests to determine the identity and concentration of individual emission products. The analyses would include (1) EPA procedures for the measurement of regulated emissions, (2) chromatographic procedures for the speciation of volatile hydrocarbon compounds, aldehydes, ketones, alcohols, ethers, and polycyclic aromatic hydrocarbons (PAHs and NPAHs), and (3) special procedures for the determination of the chemical fate of metals, halogens, and other elements of special concern when such elements are known to be present in the raw fuel or additive formulation. When applicable, evaporative emissions would also need to be generated, collected, and characterized. In the case of additives, the emissions from the respective additive/base fuel mixture would need to be compared with the emissions from the base fuel alone, in order to distinguish the additive's contribution to the emission products.

The second proposed Tier 1 requirement is a comprehensive survey of the relevant scientific literature. Both public and in-house (e.g., manufacturer or industry) sources would be included in the survey, providing a compilation of all available information from previous emission characterization and health effects testing done on the whole emissions and emission products of the fuel or additive in question or on the emissions of similar fuels and additives. For this purpose, "similar" fuels and additives would be those which meet the criteria for enrollment in the same fuel/additive group as the subject fuel or additive, pursuant to the grouping system proposed in section IV of this notice.

One of the functions of the literature search would be to determine the availability of adequate existing testing which could be submitted by manufacturers in compliance with the requirements of the registration program. If the results of the required emission characterization procedures mentioned above were already

available in the existing literature, then those procedures would not need to be repeated. Similarly, manufacturers could use the outcome of the literature search to determine the applicability of Tier 2 biological testing requirements. To the extent that the literature contained adequately conducted previous studies that conformed to the guidelines specified for any tests included in Tier 2, then such Tier 2 tests would not need to be done.

In determining whether such previous studies were adequate substitutes for conducting the Tier 2 tests, the manufacturer would need to consider a number of factors. First, the previous testing in regard to any given endpoint would have to address the effects of inhalation exposure to the whole combustion or evaporative emissions of the respective fuel or additive. Tests performed on the emissions of fuels and additives which could be classified in the same group as the subject fuel or additive would be considered relevant, but tests on products not conforming to the relevant group definition would not apply. Raw product testing, using fuels or additives in the liquid state or as whole aerosolized preparations, would not suffice. In general, inhalation studies on the individual emission products of the fuel or additive would not adequately substitute for whole emissions, unless emission characterization studies showed that an additive has only one emission product that differentiates its emissions from the base fuel. Documentation would need to be sufficient to determine that the studies were conducted in a manner consistent with generally accepted scientific principles, good laboratory practices, and the specific testing guideline in question. Important parameters would include the type and number of test subjects, the number and adequacy of dosages, the methodology and duration of inhalation exposure, and the technical methods used for monitoring the progress of the test and for analyzing the results. In general, the exposure duration would need to be at least as long as that stipulated in the specified Tier 2 guideline; however, shorter exposures would be acceptable if the test results were positive, including a demonstrable dose-response relationship. Finally, the age of the data would be a consideration. In view of technological advances and changing technical standards, older studies would be less likely to be acceptable than more recent studies. Nevertheless, the quality of the study would be the deciding factor, not the age per se. These same considerations would later be used by EPA in judging whether the submitted tests were in compliance with the program requirements.

The third proposed Tier 1 requirement would involve data analysis and modeling approaches. Appropriate methods would need to be selected and used for projecting ambient concentrations of the various emission products and for evaluating the chemical reactivity and fate of the emitted compounds in the atmosphere.

Tier 2. The second evaluation tier is composed of a series of short-term laboratory tests which comprise a minimum screening battery for the previously designated health endpoints. Most of the proposed tests involve exposure of laboratory animals to the whole emissions of fuels or additive/fuel mixtures. One exception is the Ames reverse mutation assay, which is comprised of a series of in-vitro studies utilizing bacterial substrates.

Because mutation is one of the major mechanisms involved in the transformation of normal cells to neoplastic cells, there is some overlap in the screening tests required for determining the potential carcinogenicity and mutagenicity of fuel and fuel additive emissions. Proposed Tier 2 requirements related to one or both of these two endpoints include (1) the Ames reverse mutation assay, (2) *in vivo* micronucleus assay, and (3) *in vivo* sister chromatid exchange assay. As mentioned above, the Ames assay involves *in-vitro* procedures. The other tests in this series require inhalation exposures of test animals to the emissions of the fuel or fuel/additive mixture, followed by harvesting, culture, and analysis of designated cell types.

The proposed screening tests for the other specified endpoints would generally involve the controlled exposure of test animals by inhalation to fuel or additive emissions at three different dilutions for six weeks. Following the period of exposure, relevant structures would be examined for morphologic, histologic, and functional changes related to the given endpoint. Developmental (teratogenic) effects would be studied by exposing pregnant females to emissions during the most sensitive period of pregnancy, followed by examination of the uterus and its contents just prior to the normal time of parturition. Testing for adult reproductive effects would require the exposure of rodents before and after mating and throughout pregnancy, with subsequent evaluation of the offspring as well as analysis of the reproductive organs and tissues of the adult animals.

Together with the information from Tier 1 on the composition of emissions and on the estimated chemical reactivity and potential risk of exposure to these substances, the proposed Tier 2 tests will provide a substantial body of data on the potential public health and welfare effects of the emissions produced by a fuel, additive, or group of formulations. If significant adverse effects appear very unlikely, the evaluation process would be complete at the end of Tier 2. However, if the associated risks are still uncertain, additional testing might be required under Tier 3.

Tier 3. After the results of the first two tiers have been submitted and reviewed, EPA will determine whether sufficient data are available on the health effects and exposure characteristics of the fuel/additive emissions to permit potential regulatory decisions to be made. If the information is adequate to allow EPA reasonably to conclude that the fuel or additive is quite likely to have either very low health risks or unacceptably high health risks, additional testing would probably not be required. However, if the health risk potential is still uncertain, additional studies might be required at the Tier 3 level to resolve the uncertainties. The specific Tier 3 tests required would be determined on a case-by-case basis at EPA's discretion.

While EPA will not ordinarily perform a formal risk characterization when determining whether to exercise the Tier 3 authority, both health effects data and exposure information will be considered. For example, if the potential health effects of exposure were very severe, then a need for Tier 3 would be suggested even if the exposed population were relatively small. If the potential adverse effects were more moderate or equivocal, a larger population would generally need to be at risk before Tier 3 testing would be required. Additional testing might also be required when the results of Tier 2 tests are negative (i.e., apparently non-toxic), if EPA judged that inadequate laboratory procedures or techniques interfered with the test results.

While the specific objectives and scope of Tier 3 testing would vary depending on the concerns identified in the earlier tiers, chronic (2–3 year) inhalation studies would sometimes be included. Chemical disposition studies, exposure studies, and dosimetry analyses as well as additional emission characterization requirements might also be imposed. These requirements would most often be intended as follow-up to studies included in Tier 2. However, EPA reserves the general

authority to require the evaluation of other endpoints if available information indicates that this is necessary for regulatory decision-making. For example, if the literature search suggests that the emissions of a fuel or additive are toxic to the liver or kidneys, then EPA would not be precluded from imposing hepatotoxicity or renotoxicity testing requirements under Tier 3 simply because screening studies for these endpoints were not included under Tier 2.

Section VI of this NPRM presents further discussion on the circumstances which would lead EPA to conclude that Tiers 1 and 2 provide sufficient information without invoking Tier 3, the potential criteria for imposing Tier 3 testing requirements, and the likely nature of such requirements.

4. Timing Considerations

The organization of the program's health effects evaluation requirements into hierarchical tiers ensures that the proposed rule accommodates the goals of both section 211(e) and section 211(b). Section 211(e) requires that, for existing fuels and fuel additives, the "requisite information" be furnished to EPA within three years of the implementation of the final rule. For fuels and additives not yet registered when the final rule is promulgated, submission of the required information will be a prerequisite for registration. However, section 211(e) also requires EPA to implement the authority under section 211(b), which gives the Administrator discretion to require testing to determine the potential public health or welfare effects and to "receive changes in the information required." Thus, while section 211(e) contains a time frame of three years for submission of data, it also mandates that EPA implement its broad discretionary authority to require the testing it considers necessary to assess the public health and welfare effects of fuels and fuel additives.

In 1977, Congress believed that short term testing methods would often be adequate to determine long term health effects. (See H. Rep. No. 95–294, at 309, Legis. Hist. at 2776, "However, the paramount interest in protection of public health requires that test protocols be reasonably comprehensive * * *. Relatively inexpensive but reliable test methods are increasingly becoming available for these purposes and these test methods should be utilized insofar as possible.") The proposed short term tests included in Tier 2 reflect this approach and, indeed, may often eliminate the need for further evaluation of a fuel's or additive's effects on certain endpoints.

However, these "relatively inexpensive" methods have generally not advanced to the point where they can always serve as acceptable substitutes for traditional studies entailing long term *in vivo* exposures. In some instances, the short term tests may reveal potential hazards without providing sufficient information to determine the longer term consequences of the observed effects or the extent to which they represent significant public health or welfare risks. To obtain more definitive information, tests of longer duration may sometimes be needed. For example, a higher order reproductive/developmental study would take close to a year, chronic toxicity tests might require one to two years, and carcinogenesis might not be observable until the late stages of a two- to three-year experimental exposure. The additional time required for test vehicle mileage accumulation, Tier 1 and 2 assessments, protocol development, study set-up, and results evaluation would effectively preclude submission within the prescribed three years.

Therefore, EPA has accommodated the time frame set forth in section 211(e) with the objectives of section 211(b) by using a tiered approach to testing. Data prescribed under Tiers 1 and 2 would be required to be submitted within three years of the effective date of the rule for existing products, and prior to receiving registration for new products. On the basis of such information, EPA would determine if further testing were needed under Tier 3 to assess the attendant risks. If Tier 3 testing were required, for either new or existing products (or groups), registration would be granted, but would be conditioned upon satisfactory compliance with the Tier 3 data requirements according to a timetable determined by EPA to be appropriate to these requirements. If additional testing were needed only to make up for deficiencies in information content or testing technique related to Tiers 1 and 2, then the original three-year time frame would still be in force. Notwithstanding the granting of a registration, if EPA determined that a fuel or additive was likely to present a substantial risk to the public health or welfare, then EPA could invoke available regulatory authority under other Federal law, including CAA section 211(c) or applicable sections of TSCA.

F. Scope of Welfare Effects Evaluation

Section 211(b)(2)(B) states that the Administrator may require manufacturers to furnish "reasonable and necessary" information for determining "the extent to which (fuel and fuel additive) emissions affect the public health or welfare". The term "welfare effects" refers generally to the impact which air pollution produced by motor vehicle fuels and fuel additives may have on the environment, and encompasses a broad range of effects on aquatic and terrestrial ecosystems, cultivated crops and other vegetation, natural and man-made materials, wildlife, and stratospheric ozone. Air pollution effects on the public welfare also include important environmental concerns such as noxious orders or visibility impairment, which may detract from human well-being while not representing specific dangers to human health.

A full assessment of the welfare effects of mobile-source air pollution would need to take into consideration a large number of complex and interrelated factors: the residence time of fuel and additive emissions in the air, the chemical reactions of the emissions with other air pollutants, the dispersion and deposition of the emissions and their atmospheric by products, the ability of animals and plants to bioconcentrate these substances, and the specific consequences to various ecosystems and to the public's well-being. Such avenues of investigation are extremely important to our general understanding of the causation and effects of air pollution. Future scientific study in these areas will be critical in guiding the development of general policies and effective regulatory approaches for reducing the environmental risks of air pollution.

However, at the present time, EPA proposes not to include laboratory testing for welfare effects in the requirements of the fuel and additive registration program. Except for stipulating that welfare effects requirements should be "reasonable and necessary", section 211(b) gives EPA the discretion to determine the scope of the assessment. In contrast to the provisions regarding health effects, the statue does not specifically require testing to be done to evaluate the effects of fuels and additives on the public welfare, and does not mandate specific endpoints for welfare effects assessment. At the present time, scientific experience and laboratory screening methods in this complex area are more limited than in the area of health effects. Furthermore, other EPA programs are actively involved in researching and controlling mobile and stationary source contributions to major air pollution problems such as tropospheric/stratospheric ozone, global warming, and acid rain.

For these reasons, EPA plans to address the area of welfare effects using approaches other than biological testing. Under this proposal, welfare effects requirements would include emission characterization, literature research, and modeling/analytic methods. As previously discussed, Tier 1 requires responsible producers to conduct chemical speciation procedures to identify the emission products generated by fuels and additives. These procedures will yield an inventory of potential harmful air pollutants which may have significant impacts on the general environment and public welfare as well as on the public health. Secondly, Tier 1 includes a thorough literature search for existing health-related information about the emissions of fuels and additives. This requirement will be widened to encompass available scientific literature on welfare effects, including, but not necessarily limited to, the exposure and response of plants and animals to emissions, the potential for bioaccumulation, and the concentration and persistence of the emission products in the air, soil, and water. A search of databases on environmental toxicity (aquatic and terrestrial) will be included in this requirement. Finally, the modeling requirements of Tier 1 will include analysis of the environmental partitioning and fate of fuel and additive emission products and the potential for aquatic and terrestrial ecosystem exposure. As a result of these expanded Tier 1 activites, EPA would expect to obtain useful summaries and analyses of existing data on the welfare effects of fuel and additive emissions.

While, at this time, EPA is not proposing to require biological testing for welfare effects, comments are requested on the need for and feasibility of including such tests in the program requirements. To be most useful, such comments should include specific issues to be addressed in possible welfare effects testing and practical apporoaches for examining these issues within the context of the registration program. One alternative is to retain the option of imposing welfare effects testing requirements at the Tier 3 level when the outcome of Tier 1 demonstrates both significant environmental toxicity and exposure potential. The criteria for such decisions would be similar to those used for making health-related Tier 3 decisions. Thus, Tier 3 testing for welfare effects might be required if the environmental partitioning and exposure analysis reveals the potential for broad exposure at concentrations that are likely to pose a threat to sensitive plants and animals.

If this alternative were adopted, Tier 3 welfare effects testing would be determined by EPA on a case-by-case basis. Numerous protocols are available. Endpoints of concern for aquatic, mammalian, and avian toxicology might include, but are not necessarily limited to, lethal concentrations, effects on growth and reproduction, and bioaccumulation. Plant toxicological endpoints might include growth, yield, reproduction, fruit quality, and tissue damage or loss. The exposure treatments for such tests would be administered at expected environmental concentrations.

Specific Tier 3 test requirements would be tailored to evaluate the potential environmental problems identified in Tier 1. For example, if the Tier 1 modeling results indicated that toxic emissions partitioned to air or soil and posed a risk to vegetation, Tier 3 tests on seedling vigor, life cycle, growth and reproduction, and bioaccumulation could be required to quantify the risk. Similarly, if the pollutants partitioned to water, tests relating to fathead minnow growth, reproduction, bioaccumulation, mortality, or other appropriate concerns would be required. Comment on this possible approach and other alternatives is requested.

IV. Grouping System for Fuels and Fuel Additives

A. Background and Objectives

Section 211(e) provides a number of mechanisms by which EPA can reduce the costs and burdens of compliance with the registration requirements set forth in section 211(b). In particular, section 211(e)(3)(B) permits the Administrator to "provide for cost-sharing with respect to the testing of any fuel or fuel additive which is manufactured or processed by two or more persons, or otherwise provide for shared responsibility" so that the program requirements can be met without duplication of effort. In accordance with this provision, EPA intends to establish a grouping system which would permit manufacturers of similar fuels and fuel additives, on a voluntary basis, to pool their resources and efforts in satisfying the registration requirements described in this NPRM. The groups defined by EPA in the final rule (unless modified by subsequent rulemakings) would be the only groups permitted for satisfying the requirements of the program.

To this end, proposed criteria have been developed for sorting individual fuels and additives into groups of related formulations based on similarities in their chemical/physical composition. The fuels and additives within each group are expected to have similar emission characteristics and thus essentially the same general activity with respect to their potential effects on the public health and welfare. Therefore, chemical or toxicologic information associated with individual members of a given group can reasonably be generalized to all fuels and additives in the group, and tests perfomed on selected representatives can be considered valid for the group as a whole.

While each producer of a fuel or additive would still be held individually accountable for compliance with the registration program, the grouping system would provide an opportunity for meeting the health/welfare evaluation requirements in association with manufacturers of similar products. Participation in the fuel and fuel additive groups would be strictly voluntary, and any manufacturer could choose to fulfill the requirements on an independent basis. Those who chose to take advantage of the grouping opportunity would be able to share their planning efforts, research capabilities, and financial resources in satisfying the information-gathering and testing requirements of the program. To satisfy requirements for chemical and biological testing, the required tests would be done on one or more formulations selected to represent the group, rather than being repeated for each of the fuels and additives in the group. The results of the tests on the group representative(s) would be submitted jointly for all members of the group, with applicable costs to be shared by the respective manufacturers. Manufacturers who questioned whether the results obtained for their group's representative(s) were valid for their own products could conduct confirmatory tests on their products on an independent basis and at their own cost. However, until such independent test results were made available to EPA, the original results submitted on behalf of the group would be considered valid for all member products, and could be applied by EPA in risk assessment and risk management under CAA section 211(c).

The grouping system for fuels and additives is expected to provide a number of benefits to the producers and blenders who are responsible for registration, as well as increasing the efficiency and functionality of the registration program itself. The primary objective of the grouping system is to maximize the efficiency of the program to the public, the manufacturers, and

EPA. First, the grouping system will reduce the overall costs of the registration program by avoiding the unnecessary generation and submission of essentially redundant information by individual manufacturers with similar products. In addition, by reducing the number of individual formulations that will be subject to testing, the grouping system is expected to ease the pressure and demands on scarce laboratory capacity. Group submissions of test results and other registration information will also decrease the volume of materials which EPA must review and process.

The following sections explain the logical approach and functional rationale for the proposed grouping system and individual group definitions. Rules regarding the appointment of group representatives for health effects testing are also presented. Following these sections, issues relating to the practical implementation of the grouping system are discussed.

B. Grouping System Rationale

1. Emissions vs. Raw Product Basis

Because the information and testing provisions of the registration program are focused on air pollution effects, the fuel/additive groups would ideally be defined according to the emission products of the fuels and additives rather than the chemical composition of the raw (uncombusted) fuel and additive formulations. Unfortunately, the emissions data needed to define and carry out an emissions-based grouping system will not be available until the final rule related to this NPRM has been implemented and the new registration requirements have been completed by fuel and additive producers. Thus, the groupings presented in this proposal have been defined according to characteristics of the raw fuels and additives. EPA believes this to be a reasonable approach, based on the principle that similar raw formulations are expected to generate similar emission products and, furthermore, that the variability which may exist between similar fuels and additives will be reduced by the process of combustion. Comments are requested on the validity of using raw product characteristics as the fuel/additive grouping criteria for this emissions-based testing program and the adequacy of this grouping approach for evaporative as well as combustion emissions. If subsequent information indicates that the original groupings are inadequate, EPA reserves the authority to modify them to better reflect similarities in emission characteristics. In addition, the grouping system will be updated as necessary to accommodate unanticipated fuel and/or additive formulations which may be introduced in the future. Such changes would be implemented by appropriate rulemaking procedures.

2. Fuel/Additive Relationships

Because all fuel producers or blenders and all additive producers are individually responsible for registering their products, the possibility of duplicative testing for related fuels and additives is a problem inherent to the registration program. Registered fuel formulations nearly always contain a complement of "bulk" additives, including performance boosters, detergents, rust inhibitors, and other agents. In fact, the basic registration information submitted for most existing fuels has typically included a list of many alternative "substantially similar" additives within each purpose-in-use category, any of which may be contained in various formulations of the commercially distributed fuel. At the same time, these bulk additives must also be separately registered by their original producers, and are subject to the same health/welfare effects evaluation procedures that the related fuels must undergo. In meeting the requirements of this NPRM, each bulk additive must be mixed with an associated fuel prior to generating emissions for testing. To the extent that the resulting additive/fuel mixture is similar to existing formulations of fuels (with their bulk additive components), the health effects tests conducted on the emissions of the additive/fuel mixture would be duplicative of existing or new tests conducted on the related fuels themselves.

Similar overlap exists for aftermarket additives which are "substantially similar" to their respective fuels. As in the case of bulk additives, aftermarket additives must be mixed with the appropriate fuel prior to generating the emissions which will be subject to testing under this program. If the composition of the additive/fuel mixture closely resembles that of the fuel alone, testing efforts for the additive and the related fuel formulation will be redundant. The likelihood of redundant efforts is increased by the fact that it is the fuel/additive emissions rather than the raw fuels and additives which are subject to the proposed testing requirements.

To avoid these potential duplication problems, the proposed grouping system does not require closely-related fuels and additives to be segregated into separate groups. When the combination of an additive and its respective fuel results in a mixture that is essentially the same as typical commercial formulations of that fuel, then the additive and associated fuels are grouped together. Thus, the producers of the fuels and the related additives can fulfill their individual registration responsibilities through jointly-supported testing of one or more formulations representative of their group rather than through duplicative independent efforts. That is, the requirements for additives which are registered as part of a fuel formulation can be met in conjunction with the fuel producers. Furthermore, other bulk or aftermarket additives which have essentially the same chemical makeup as additive components of fuel formulations can also meet their requirements in conjunction with these fuel products.

By grouping similar fuels and additives together, the proposed grouping scheme also avoids the need to define each generic product or product component arbitrarily as either a "fuel" or an "additive". This problem would otherwise arise when a given substance (or mixture) can serve as either a fuel or an additive.

A good case in point is methanol. Methanol can function as a "substantially similar" additive to unleaded gasoline or, at higher concentrations, as the oxygenating additive agent in "reformulated" gasoline or diesel fuels. On the other hand, there are dedicated methanol-fueled vehicles as well as variably- and flexibly-fueled vehicles which can make use of methanol as their basic propellant, in such form as 100 percent methanol fuel (M100) or fuel composed of 85 percent methanol and 15 percent gasoline (M85).

The approach taken in the development of the proposed grouping system recognizes that fuel and additive formulations are complex mixtures of varying proportions rather than pure chemical substances. The proposed grouping system seeks to categorize fuel and additive products according to their expected in-use combinations. To the extent possible, it does not make grouping decisions based upon sometimes artificial distinctions between fuels and additives. This categorization process is further explained in the next section.

3. Grouping Approach

The basic conceptual framework for the proposed grouping system is illustrated in Figure 2. In essence, EPA has specified seven broad "fuel families" and three general "formulation

classes. The criteria which define the formulation classes" are used to subdivide the fuel families into a series of "fuel/additive categories." Another way to view this relationship is in the form of a cross-tabulation, as shown in Figure 3. Here, the fuel families serve as column headings and the formulation classes describe the rows. The resulting combinations of fuel families and formulation classes (i.e., the boxes in Figure 3) are the fuel/additive categories.

Within each category, EPA has developed criteria for further subdividing the products into "fuel/additive groups". These groups are the working units of the grouping system: it is among the members of the fuel/additive groups that cooperative evaluation and testing efforts can be pursued using designated group representatives.

This conceptual framework provides some important practical benefits. First, it avoids the need to anticipate and attempt to define all of the possible fuel and additive groups which might be required. Instead, generic rules for categorization and grouping are proposed, and specific fuel/additive groups are created in response to the product components encountered. The proposed framework should also facilitate the manufacturer's task of assigning a given fuel or additive to the appropriate group. The first step would entail the selection of the applicable fuel family and formulation class for the product according to criteria discussed below. These selections would define the proper fuel/additive category for the product. Criteria within each category would then be used to determine the appropriate group assignment. After the group had formed and arrangements made for cooperative testing efforts, applicable criteria would be applied to select a representative of the group to be used in group-sponsored testing.

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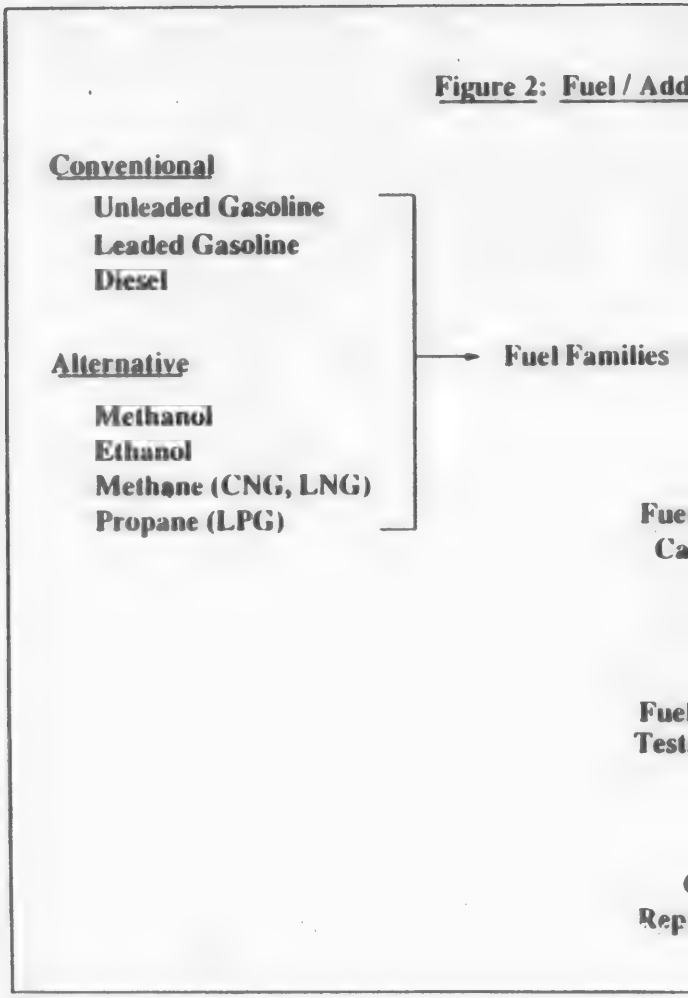

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Additive Classification Hierarchy
ies
X
Formulation Classes
Baseline
Non-Baseline
Atypical
Fuel / Additive
Categories
Fuel / Additive
Testing Groups
Group
Representatives

FIGURE 3.—FUEL/ADDITIVE CATEGORIES

	"Conventional" fuel families			"Alternative" fuel families			
Formulation classes	Unleaded gasoline (A)	Leaded gasoline (B)	Diesel (C)	Methanol (>=50% MeOH BY VOL) (D)	Ethanol(>=50% EtOH BY VOL) (E)	Methane (CNG, LNG) (F)	Propane (LPG) (G)
(1) Baseline formulations.	Baseline unleaded gasoline category. One group represented by unleaded base fuel.	Baseline leaded gasoline category. One group represented by leaded base fuel.	Baseline diesel category. One group represented by diesel base fuel.	Baseline methanol category. Two groups (M96–M100 and M50–M95) represented by M100 and M85 base fuels.	Baseline ethanol category. Two groups (E96–E100 and E50–E95) represented by E100 and E85 base fuels.	Baseline methane category. Two groups (CNG and LNG) represented by CNG and LNG base fuels.	Baseline propane category. One group represented by LPG base fuel.
(2) Non-baseline formulations.	Non-baseline unleaded gasoline category. Grouped according to presence of non-baseline factors.	Non-baseline leaded gasoline category. Grouped according to presence of non-baseline factors.	Non-baseline diesel category. Grouped according to presence of non-baseline factors.	Non-baseline methanol category. Groups TBA.....	Non-baseline ethanol category. Groups TBA.....	Non-baseline methane category. Groups TBA.....	Non-baseline propane category. Groups TBA.
(3) Atypical formulations.	Atypical unleaded gasoline category. Grouped according to atypical elements and other characteristics.	Atypical leaded gasoline category. Grouped according to atypical elements and other characteristics.	Atypical diesel category. Grouped according to atypical elements and other characteristics.	Atypical methanol category. Groups TBA.....	Atypical ethanol category. Groups TBA.....	Atypical methane category. Groups TBA.....	Atypical propane category. Groups TBA.

*Each category contains one or more fuel/additive groups. Health effects testing information is required for each such fuel/additive group.

The key parameters and relationships within this grouping framework are further explained below.

Fuel families. Three "conventional" and four "alternative" fuel families have been defined. Each family consists of a constellation of fuel and additive products which share basic characteristics in regard to their chemical/physical properties and engine/vehicle applicability. The seven fuel families, represented as columns A–G in Figure 3, are: (a) Unleaded gasoline, (b) leaded gasoline, (c) diesel, (d) methanol (containing at least 50 percent methanol by volume), (e) ethanol (containing at least 50 percent ethanol by volume), (f) methane (i.e., compressed natural gas and liquefied natural gas), and (g) propane (i.e., liquid petroleum gas). As shown in Figure 3, the unleaded gasoline, leaded gasoline, and diesel families are regarded as the "conventional" fuel families, while the remaining four are referred to as the "alternative" fuel families.

EPA expects to define additional fuel families in the future as the need arises. For example, hydrogen-based fuels have not been included in the current framework because motor vehicle hydrogen fuels and corresponding hydrogen-fueled engines are not expected to be commercially available for several years. However, EPA requests comments about the possible need for hydrogen or other additional fuel families at this time.

As noted above, a fuel family has been defined for leaded gasoline and associated additives. However, provisions in the 1990 Amendments to the Clean Air Act prohibit the manufacture or sale of new leaded-fueled motor vehicle engines beginning with model year 1993, and ban the sale of leaded fuels for on-road use as of January 1, 1996. Thus, leaded fuels and additives will be phased out at about the same time that data would be submitted under today's proposed rule. In view of the upcoming constraints on leaded products and the timing of the new registration program's implementation, comment is requested about the need to include these products in the grouping system or, indeed, in the new ristration program itself.

Consistent with the previous discussion on fuel-additive relationships, each fuel family includes not only the fuels referenced in the name of the family, but also bulk and aftermarket additives which are intended for use in such fuels. Additives which can be used in conjunction with more than one type of fuel are proposed to be assigned to the relevant fuel family of which the most gallons of fuel are sold relative to the other applicable fuel families. An alternative approach would require such additives to be tested in association with all relevant fuel families. Comment is requested on this alternative, including the expected costs and benefits relative to the proposed approach.

EPA plans to develop sets of chemical and physical specifications which will represent theoretical "industry average" formulations for each defined fuel family. These generic formulations, called "base fuels" (which will include a minimal additive package), will function as archetypes of the fuels and additives in their families. For fuel additives, determination of the proper category and group is to be based on the properties of the additive/base fuel mixture that would result if the additive were mixed in its family's base fuel at the maximum concentration recommended by the additive manufacturer. Moreover, prior to the generation and testing of additive emissions, the additive is to be mixed in its base fuel at this concentration. Tests conducted on the emissions of the base fuel would then serve as controls against which tests on the emissions of the additive/base fuel mixture would be compared. Base fuels are also proposed to serve as representatives in compliance with testing requirements for some fuel/additive groups. Further discussion on the definition and use of base fuels is presented in section V.E of this NPRM.

Formulation classes. The formulation classes serve to subdivide the fuels and additives in each family into categories according to their similarity to the base fuel(s) specified for the family. Displayed as rows 1–3 in Figure 3, three formulation classes have been defined: "baseline", "non-baseline" and "atypical".

(1) The baseline formulation class (row 1 of Figure 3) consists of fuels and associated fuel additives which resemble the respective base fuels in terms of their elemental composition and their conformity with certain quantitative limits for particular elements, compounds, or characteristics. Baseline formulations in the unleaded gasoline and diesel families, for example, would contain no elements other than carbon, hydrogen, nitrogen, oxygen, and sulfur, with limitations on the allowable content of oxygen, sulfur, and other specified components.

(2) Fuels and fuel additives in the non-baseline class (row 2 of Figure 3) would contain no elements other than those allowed in the baseline class; however, they would exceed the concentration limits for certain components (or the limits on other physical/chemical characteristics) which were established for the baseline class. For fuel additives, this determination would be based on the characteristics of the mixture which would result if the additive were mixed in the appropriate base fuel at the maximum concentration recommended by the additive manufacturer.

(3) The "atypical" formulation class (row 3 of Figure 3) consists of fuels and fuel additives which depart further from their respective base fuels in that they contain elements other than those present in the base fuel or exceed specified limits on the amount of sulfur allowed. Thus, in the unleaded gasoline family, "atypical" formulations would be those containing elements other than carbon, hydrogen, oxygen, nitrogen, and sulfur and those which exceed the maximum sulfur content specified for baseline formulations. Examples of fuels and additives which would potentially fall into the "atypical" formulation class include those containing compounds such as methylcyclopentadienyl-manganese-tricarbonyl (MMT), organocerium alkanediols, hexafluoro-ethylene diamines, cobalt chloride and other halogenated metal oxides, zinc or magnesium sulfonates, ferrous or copper sulfates, boron succinamide, and many others.

For the most part, the characteristics which define the "atypical" formulation class are relatively distinct. In contrast, the separation between the baseline and non-baseline classes is less obvious. The distinction between these two classes depends on relative amounts of certain components, not the absolute presence or absence of such components. Since these components may be present along a continuum of concentrations, it is necessary to establish cut-off points which would define the amounts considered appropriate to the baseline and non-baseline formulation classes.

In regard to the "conventional" fuel families (gasoline and diesel), EPA is considering two basic alternatives for distinguishing the baseline and non-baseline formulation classes. Comments are requested from the public on the advantages and disadvantages of each. For ease of reference, these two alternative approaches are termed Option A and Option B in the discussion which follows.

Under Option A, baseline and non-baseline formulations would be differentiated on the basis of their oxygen and methanol content. In regard to oxygen, the baseline class would be restricted to formulations having less than 1.5 weight percent of oxygen, while formulations with 1.5 percent oxygen or more would fall into the non-baseline class. Because the cut-off point of 1.5 percent is consistent with the proposed minimum oxygen requirement for reformulated gasolines, all reformulated gasolines would be assigned to the non-baseline formulation class under this option.

The baseline constraint on methanol content under Option A would correspond to the methanol limitations for "substantially similar" fuels (56 FR 5352, February 11, 1991): 0.3 percent methanol by volume or, if accompanied by an equal volume of butanol or higher molecular weight alcohol, up to 2.75 percent methanol. Formulations which exceed these methanol limitations would fall into the non-baseline class.

Option B would also take oxygen and methanol content into account in distinguishing baseline from non-baseline formulations, but would establish different cut-off points for these factors. The preliminary baseline limitations on both oxygen and methanol content under Option B would correspond to the limitations on these substances in the "sub sim" rule: oxygen would be limited to 2.7 weight percent and methanol would be subject to the limits cited above for Option A. However, fuels and additives which exceed these "sub-sim" oxygen or methanol limits, but have been waivered from associated section 211(f) restrictions, would also be included in the baseline formulation class. Reformulated fuels would thus be considered baseline formulations under Option B. The non-baseline formulation class under Option B would contain fuels and additives which are not "sub sim" and have not been waivered under section 211(f). (It is important to recognize that any fuel or additive containing an "atypical" element would be assigned to the "atypical" formulation class, whether or not it has received a section 211(f) waiver.)

Under both Options A and B, distinctions between baseline and non-baseline formulations are also under consideration for other fuel and additive characteristics, including limits on the permissible levels of compounds such as aromatics, olefins, and PAHs, as well as physical characteristics such as T90 (the temperature at which 90 percent by volume of a liquid is evaporated). EPA asks for comment on whether formulations with relatively high levels of these substances or characteristics should be assigned to the non-baseline class and, if so, what specific cut-offs should be established for making the baseline/non-baseline determinations. EPA also asks for comment on whether the baseline oxygen limitation is appropriate under Option B; or whether tighter restrictions should apply, as under Option A. To be able to assess these options and alternatives, however, their potential implications for the fuel/additive categories and groups must first be understood. These relationships are described in the following sections.

Categories. As mentioned previously, the fuel/additive categories are equivalent to the "boxes" in a cross-tabulation defined by the intersection of the seven fuel families and the three formulation classes. For example, as displayed in the first column of Figure 3, the unleaded gasoline fuel family is subdivided into baseline, non-baseline, and "atypical" fuel/additive categories by the three formulation classes. Some of the categories shown on Figure 3 have been defined in anticipation of future product introductions and registration designations under section 211(a), and may not have immediate applicability to the proposed new registration program.

The precise specifications of the three categories in the unleaded gasoline fuel family will depend on whether the baseline and non-baseline formulation classes are defined by Option A or Option B. Under either option, the definition of the baseline unleaded gasoline category would incorporate some of the criteria which define "substantially similar" products. Fuels and additives in the baseline unleaded gasoline category would (1) contain no elements other than carbon, hydrogen,

nitrogen, oxygen, and/or sulfur, in the form of hydrocarbons, aliphatic ethers, and/or aliphatic alcohols, [2] contain no more than 0.3 percent methanol by volume or, if accompanied by an equal volume of butanol or higher molecular weight alcohol, up to 2.75 percent methanol, [3] contain no more than 1,000 ppm sulfur, and [4] meet applicable volatility class standards published by the American Society for Testing and Materials (ASTM D4814).

If Option A were adopted, one additional restriction would apply to fuels and additives in the baseline unleaded gasoline category: Their oxygen content would be limited to an amount less than 1.5 weight percent. If Option B were adopted instead, two other specifications would apply. First, oxygen content would be limited to 2.7 weight percent or less. Second, fuels and additives which exceeded the limitations on oxygen or methanol content, but received a waiver under section 211(f) for these "non-sub-sim" characteristics, would be included in the baseline category, as long as all other baseline criteria were met. Additional specifications would need to be established for the baseline unleaded gasoline category if restrictions were set on the aromatic, olefin, or PAH content, or on the basis of T90.

Unlike the "sub sim" interpretive rule, the specifications proposed for the baseline unleaded gasoline category do not include separate criteria for fuel additives. In this program, classification decisions for additives are to be based on the properties of the respective additive/base fuel mixture. Thus, the criteria used for sorting fuels into categories and groups can also be used for additives.

The non-baseline unleaded gasoline category is comprised of fuels (and additive/base fuel mixtures) which fail to conform to the baseline designation because their oxygen and/or methanol exceeds the baseline constraints. Under Option A, this category would include formulations of at least 50 percent unleaded gasoline blended with methanol, ethanol, methyl-tertiary-butyl ether (MTBE), ethly-tertiary-butyl ether (ETBE), and/or other alcohols and ethers, when the total oxygen content is at least 1.5 percent. Thus, the non-baseline category would include reformulated gasolines as well as a number of formulations which have previously been granted waivers of section 211(f) restrictions. In contrast, under Option B, these reformulated and waivered gasolines would fall into the baseline category. The non-baseline category under Option B would, for the most part, include gasoline formulations with oxygen or methanol in excess of waivered amounts. Under either option, the non-baseline category could contain additional fuels and additives if the other parameters previously discussed were also included in the definition of the non-baseline formulation class.

The third or "atypical" category in the unleaded gasoline fuel family includes fuels and additives which contain elements other than those in the baseline category. Thus, the "atypical" elements are those other than carbon, hydrogen, nitrogen, oxygen, and sulfur. Sulfur at concentrations greater than 1,000 ppm is also considered to be an atypical element. In many instances, products containing these elements are "grandfathered" aftermarket additives which were allowed to be registered, without consideration of their possible emission control or other effects, prior to the enactment of the 1990 CAA Amendments. To generate the emissions from such additives for subsequent emission characterization and health effects testing, the additives will be required to be mixed with the base fuel designated for the fuel family. The results obtained for the emissions of the additive/base fuel mixture will then be required to be compared to control studies conducted on the emissions of the base fuel alone.

The fuel/additive categories in the leaded gasoline fuel family are conceptually similar to the unleaded gasoline categories. The definition of the baseline leaded gasoline category would be the same as that for unleaded gasoline, except that the criteria would include allowable lead content and typical halogenated lead-scavenger compounds. The non-baseline leaded gasoline category would include products which exceed the baseline limits on oxygen or methanol.

Criteria for the baseline diesel category would also parallel those specified for unleaded gasoline, except that the limit on sulfur content would be 0.05 weight percent instead of 1,000 ppm and the applicable ASTM standard would be ASTM D975. However, the definition adopted for the final rule will depend on the suitability for this purpose of the new "sub sim" criteria now under development for diesel products (see advanced notice of proposed rulemaking, 56 FR 24362, May 30, 1991). The non-baseline diesel category would contain products which exceed the applicable baseline restrictions. Potentially, these would be the same as "non-sub-sim" diesel fuels and additives. The "atypical" categories of leaded gasoline and diesel products would include products with elements other than those allowed in the respective family's baseline category or with sulfur in excess of the baseline limitations.

Categories within the "alternative" fuel families are shown in columns D–G on Figure 3. The baseline categories would contain typical M100 and M85 formulations within the methanol fuel family, E85 and E100 formulations within the ethanol fuel family, compressed and liquified natural gas formulations within the methane fuel family, and liquid petroleum gas within the propane fuel family. There is little prospective information regarding "non-baseline" or "atypical" products which may be introduced in these fuel families and it is possible that these categories will initially be empty.

Nevertheless, the boundaries between the baseline and the other potential categories within these four fuel families must be established. EPA is considering various sets of existing and proposed criteria for this purpose, including draft ASTM standards for alternative fuels and commercial specifications for alternative fuels proposed by the California Air Resources Board (CARB).[8] Some of these proposed specifications are summarized in the following paragraphs. However, the baseline category definitions which EPA adopts for the final rule may vary from these proposals, depending on the final standards and specifications promulgated by these and other organizations and the relative applicability of any "sub sim" criteria for alternative fuels which EPA may promulgate in the interim.

Within the baseline methanol category, M100 fuels are proposed to contain a minimum of 96 volume percent methanol. Up to 2 percent by mass may be composed of other oxygenate compounds (e.g., other alcohols and ethers) and up to 2 percent may be composed of hydrocarbons. The sulfur content of M100 fuel, according to a pending ASTM proposal, would be limited to 100 parts per million by weight (ppmw). M85 fuels would contain a minimum of 85 percent methanol by volume. The remaining volume would be composed of commercial unleaded gasoline under the CARB proposal, or of unspecified hydrocarbons according to the draft ASTM standards. CARB proposes a maximum sulfur content for

[8] Francis, Stephen R. Staff Report: Initial Statement of Reasons for Rulemaking. Public Hearing to Consider Adoption of Specifications for Alternative Fuels for Motor Vehicles. State of California Air Resources Board (CARB), Stationary Source Division, October 28, 1991.

M85 of 150 ppmw because of the unleaded gasoline component of the fuel, while a 50 ppmw limit is proposed by the Motor Vehicle Manufacturers Association for certification M85 fuel. All baseline methanol fuels would be required to contain a flame luminosity additive for safety reasons, due to the virtual invisibility of a methanol flame. The allowable composition of this additive would need to be determined for the final definition of the baseline methanol category.

Specifications for the baseline ethanol category would closely parallel the criteria for baseline methanol fuels, except that the ethanol must be denatured with commercial unleaded gasoline before being used in motor vehicle fuels. E100 would be required to have a minimum of 92 volume percent ethanol (98 volume percent denatured ethanol), with a maximum sulfur content of 100 ppmw. E85 would consist of a minimum of 81 volume percent ethanol (85 volume percent denatured ethanol), with sulfur content limited to 150 ppmw.

In the baseline methane category, compressed natural gas (CNG) and liquified natural gas (LNG) differ only in the manner in which they are transported and stored. Otherwise, both CNG and LNG fuels would be required to contain at least 88 mole percent methane, with 6 mole percent ethane allowed. Inert gases, principally CO_2 and N_2, could comprise up to 5 mole percent of the fuel and "other hydrocarbons" could make up a further 3.5 mole percent.

Liquified petroleum gas (LPG), or propane gas, would be required to contain, at a minimum, 80 percent propane by volume. CARB proposes that it also contain a maximum of 10 volume percent propene, while ASTM supports a maximum of 5 volume percent. The limit for butane and other hydrocarbons is proposed to be 2.5 volume percent and the sulfur content is restricted to 123 ppmw.

Comments and suggestions are requested regarding the most appropriate criteria for distinguishing the baseline, non-baseline, and atypical categories within the alternative fuel families. As EPA acquires additional data on alternative fuel and additive formulations, this information will be placed in the docket and made available for public inspection.

Groups. The fuel/additive groups are subdivisions of the fuel/additive categories, and represent the final level of product classification within the grouping system. These groups are the actual operating units of the grouping system. Within each group, one or more formulations will be chosen to represent all of the member products in compliance with the registration program's testing requirements. Related costs will be shared by participating blenders and manufacturers.

The number of groups defined in a particular category of fuels and additives depends on the variability among the potential products in that category and the likelihood that this degree of variability would cause important differences in their emission products. The magnitude of expected variability in the emissions of different fuels and additives must also be viewed in relation to the variations that will inevitably be introduced by the emission generation system itself. A single fuel/additive formulation will yield somewhat different emission products depending on the vehicle and engine used to generate them, and may even differ when the same vehicle is used under different operating conditions. Thus, absolute precision is not a logical goal. Instead, the objective underlying the group definitions is to sort fuels and additives together when it is reasonable to assume that their emission products would be essentially the same on a qualitative basis.

Given these considerations, the proposed groups and group representatives within each of the fuel/additive categories are described in the following sections.

(a) *Groups within the baseline "conventional" categories.* EPA is initially proposing that the baseline categories in the unleaded gasoline, leaded gasoline, and diesel fuel families (row 1, columns A–C on Figure 3) each be regarded as equivalent to a single fuel/additive group. EPA further proposes that each of these groups be represented in required emission characterization and health effects tests by the base fuel designated for the respective fuel family. Under this proposal, the baseline conventional fuel/additive groups would be very large, and each of the respective base fuels would potentially be used to represent hundreds of products. Thus, two alternative approaches are under consideration.

The first alternative would retain the concept of a single group for each baseline fuel/additive category, but would increase the number of representatives for each such group. For example, the baseline unleaded gasoline group might be represented by three base fuels, corresponding to regular, mid-grade, and premium formulations. Likewise, the diesel group might be represented by both D–1 and D–2 base fuel formulations. In addition, appropriate commercial formulations could be selected as representatives reflecting extremes in aromatic, olefin, or PAH content. If the baseline categories and groups were defined under Option B, consideration might also be given to the designation of selected oxygenated fuels as additional group representatives.

In practice, however, the designation of more than one representative per group would run counter to the general approach in the program that adequate existing information for any product in a given group can be used to satisfy the associated testing requirement for all products in the group. If adequate testing had previously been done, say, on one of the representatives of a group, these test results could be applied to all products in the group, including the other representatives. Therefore, full testing would not be required for each representative.

The second alternative would avoid this result by splitting the baseline fuel/additive categories into more than one group. Under this approach, the baseline unleaded gasoline category could be divided, say, into three groups (regular, mid-grade, and premium) and the diesel category into two groups (D–1 and D–2). Other groups, based on the factors previously discussed, would also be possible. A corresponding base fuel or selected member product would be designated to serve as the representative for each group. This approach would require the submittal of a complete set of test information, either existing or new, for each of these classifications. However, most of the previous testing on products in the baseline categories has made use of regular gaoline and D–2 diesel fuels. As a result, the other potential groups in these categories would largely be precluded from using existing test data for compliance with program requirements. EPA asks for comment on these various options for defining the baseline conventional fuel/additive groups and their representatives.

(b) *Groups within the non-baseline "Conventional" categories.* EPA proposes to subdivide the non-baseline categories of unleaded gasoline, leaded gasoline, and diesel products (row 2, columns A–C on Figure 3) into different working groups based on the specific compound(s) present in the formulation. In the non-baseline unleaded gasoline category, for example, separate groups are proposed for gasoline formulated with methanol alone, ethanol alone, MTBE alone, ETBE alone, and other individual alcohols and ethers. Products containing combinations of oxygenate compounds would be assigned to

additional groups, with separate groups defined for each combination present in one or more product formulations. Among currently registered fuels and fuel additives, EPA estimates that this proposal would produce 17 groups in the non-baseline unleaded gasoline category and one group in the non-baseline diesel category, assuming Option A were used to define the formulation classes.

Within each of these groups, the member fuel or additive/base fuel mixture containing the highest total weight percent of oxygen would serve as the group representative. In case of "ties" within a given group, the proposed regulations contain decision criteria for selecting the representative product based on the proportion of the total oxygen content which is contributed by particular oxygenate compounds. The proposed criteria give precedence to oxygenate compounds in the following order:

(1) Methanol,
(2) Ethanol,
(3) Tert-butyl alcohol (TBA or GTBA),
(4) MTBE,
(5) Tert-amyl-methyl-ether (TAME),
(6) ETBE,
(7) Isopropanol,
(8) Isopropyl ether,
(9) Other alcohols,
(10) Other ethers.

Some would argue that the groups proposed within the non-baseline categories are so narrowly defined that, in some cases, the exhaust emissions from products in different groups will probably be indistinguishable. At the current time, EPA is unaware of detailed emission speciation tests on various oxygenated formulations which would support this theory. However, it might be possible to establish programmatic mechanisms which would allow some groups to be collapsed for purposes of studies on the health effects of combustion emissions, if the results of speciation tests indicated that the emissions from the representative products in different groups were the same. Such mechanisms would need to include speciation results on the emissions from a sufficient number of vehicles that objective statistical conclusions could be reached regarding the emissions variability. Comments and suggestions on these issues are welcome.

Depending on the final definitions adopted for the baseline and non-baseline formulation classes, the non-baseline categories may contain fuels and additives with distinguishing characteristics other than oxygenate components. As mentioned previously, three such factors under consideration are aromatic, olefin, and PAH content. In these instances, the definition of groups and group representatives would follow principles similar to those applied above. To use aromatic content as an example, and applying the principles presented in the supporting regulatory text, individual compounds of concern would be grouped separately; however, if two compounds of concern were present, the representative would be that with the greater proportion of the heavier weight aromatics (e.g., greater weight given to nine-carbon than seven-carbon compounds).

(c) *Groups within the "Atypical" gasoline and diesel categories.* For fuels and additives in the "atypical" gasoline and diesel categories (row 3, columns A–C on Figure 3), EPA proposes to define a relatively large number of distinct groups according to the element(s) which caused these products to be categorized as atypical. First, separate groupings would be established for any single atypical element and any unique combination of atypical elements which occurred among the products in each category. These groupings would then be further subdivided according to the presence or absence of polymers and the presence or absence of oxygen in an amount greater than the baseline amount.

For currently registered fuels and additives, EPA estimates that this approach would result in 48 "atypical" unleaded gasoline groups and 47 "atypical" diesel groups. Comments are requested concerning this proposed grouping scheme and possible alternative approaches. For example, comment is requested on the necessity of establishing separate groups for each unique combination of "atypical" elements and conditions, as is proposed. Alternatively, it might be possible to define some reasonable rules of precedence which would allow products containing certain combinations of "aytpical" characteristics to be grouped with products containing only one of these characteristics. Such an approach would decrease the total number of groupings and would increase the number of potential products in each group. Suggestions are also welcome in regard to additional variables (e.g., aromatic content or the presence of specific oxygenate compounds) which should be taken into account in defining groups of atypical products, recognizing that each new factor could increase the number and decrease the size of the resulting groups.

For each group, the representative to be used in satisfying the group's testing requirements is proposed to be the member product with the highest concentration of atypical elements. In case of ties, a process for selecting the representative is proposed which would give precedence to the relevant characteristics in the following priority order:

(1) Total metals,
(2) Total halogens,
(3) Total of other atypical elements,
(4) Total oxygen content,
(5) Polymer content.

EPA has proposed that the representative be selected to reflect the highest concentration of atypical elements so that, if subsequent tests are negative, these results can safely be generalized to all group members. If, instead, the representative were chosen to reflect the average or median concentration of atypical elements among products in the group, the significance of negative test results would be unclear for group members with higher concentrations of atypical characteristics. In case a particular group contains products which generally reflect a distinct clustering of concentrations plus one or more products with much higher concentrations, the associated manufacturers may choose to divide the group on this basis to prevent a distant "outlier" from serving as the representative for all.

(d) *Groups within the baseline "Alternative" Categories.* Within the baseline methanol category, EPA proposes to establish two fuel/additive groups. One group would include M100 formulations (containing at least 96% methanol) and would be represented by a designated M100 base fuel formulation. The second group would consist of methanol/gasoline blends containing 50–96% methanol. The latter group would be represented by a designated M85 base fuel, reflecting the expected preponderance of end-use formulations in this group.

Because EPA has little experience with formulations in the ethanol, methane, and propane fuel families, suggestions from the affected industry organizations are requested in regard to appropriate numbers of groups and representatives for the baseline category in each of these families. At this time, EPA proposes to define two groups within the baseline ethanol category, defined in parallel to the two methanol groups described above. The baseline methane category is also proposed to contain two groups (CNG and LNG), while the baseline propane category would constitute a single group. Depending on the rapidity with which products in these categories are introduced into the marketplace, and the timetable for implementation of

expected regulations requiring the registration of these products, it may be possible to define baseline ethanol (E85 and E100), CNG, LNG, and LPG formulations to serve as the respective group representatives in time for the final rule related to this proposal. Alternatively, if products in these groups are not registered until after publication of the final rule, it may be necessary to designate the first commercial fuel to seek registration in each group as the prospective representative for similar products seeking registration at a later time. In that instance, technical amendments could be published defining the specific product formulation criteria which would be used to determine when producers of later products could rely on the testing information submitted for the first product in satisfaction of their own registration requirements. A time limit for the initial registrant's right to reimbursement would also need to be established. Comment is solicited on these topics.

(e) *Groups within the "Non-Baseline" and "Atypical" "Alternative" categories.* With respect to products which may fall into the "non-baseline" and "atypical" methanol, ethanol, methane, and propane categories (rows 2 and 3, columns D–G on Figure 3), EPA must defer the devlopment of applicable groups until information on the nature of these future products becomes available. As a practical matter, such groups are likely to be defined in response to proposed new product introductions rather than in advance of their introduction. As described above in regard to the baseline alternative fuels, the first manufacturers of atypical products in these categories to satisfy the testing and other registration requirements would have the right to seek reimbursement from manufacturers of other products who wished to rely on the first manufacturer's data for registering subsequent similar products. EPA would welcome comments on these proposals and on alternative mechanisms for defining and establishing groups within these new fuel/additive categories.

4. Alternatives for Group Responsibilities

In the approach described above, a designated representative would represent the members of a fuel/additive group in compliance with all health effects testing requirements, including both the Tier 1 requirements for chemical speciation of emissions and the biological testing requirements of Tiers 2 and 3. An alternative approach would require all unique fuel and additive formulations to undergo emission characterization independently, applying the group representative principle only in regard to biological testing requirements. This approach would provide more definitive information on the emission products of each fuel and additive, but would increase program costs to individual manufacturers and would increase demands on scarce commercial laboratory capacity. EPA requests input from the public on the likely benefits and costs of imposing separate emission speciation requirements for each fuel and additive as compared to requiring the emissions data only for the designated group representative.

C. Grouping System Implementation Issues

The practical implementation of the grouping system involves two major tasks: the organization and administration of group functions, and the development of equitable arrangements for cost sharing. Backed by its experience with respect to the TSCA testing program, EPA believes that the fuel/additive industry, under the aegis of its various trade associations or other third parties, is capable of accomplishing these tasks with little or no Agency assistance and interference. However, effective operations will be critical to the overall success of the grouping provisions of the registration program, and suggestions from the industry are invited as to practical ways in which EPA may be able to facilitate the implementation of the rule.

1. Organizational Tasks

The primary organizational task is the formation of consortiums of refiners and manufacturers whose products are potential members of the same EPA-defined fuel/additive groups. This task will entail the development of procedures which will allow manufacturers who wish to participate in group functions to locate and form working associations with other manufacturers of products which fit the same grouping criteria. While willing to provide a limited amount of support, information, and guidance when necessary, EPA does not intend to determine the proper group for each fuel and additive, nor to inform the manufacturer of that group assignment. Rather, manufacturers will be expected to determine the appropriate groups for their products independently, according to grouping criteria published in the final rule, and to enroll their products into those groups under industry-sponsored brokering mechanisms. EPA expects manufacturers to comment on the grouping scheme in this proposal and does not intend to address special requests for exceptions to the grouping scheme after the final rule is promulgated.

Once the group members have been identified, administrative agreements will need to be reached concerning the division of responsibilities among the respective manufacturers for meeting the specific requirements of the registration program and for preparing the joint submittal of test results and other information to EPA. To meet the program's literature search requirements and to document the extent to which existing test results are adequate to mitigate new testing requirements, arrangements may be needed for sharing in-house health effects test data and compiling additional information from published sources. For new testing, administrative arrangements will need to be reached with respect to the selection and/or formulation of the designated representative product(s) to be tested, the acquisition of vehicles required for emission generation, the identification of qualified personnel and laboratories to conduct the tests, and the establishment of quality assurance mechanisms which will ensure that procedures and protocols are performed according to acceptable standards. Some groups, especially those in the baseline conventional fuel/additive categories, will potentially be very large, and considerable coordination effort may be required.

The task of organizing the fuel/additive groups will be complicated by the fact that the respective producers will sometimes be competitors in the same specific market segment, and that even the identification of a product as a potential member of a given group may reveal information that a producer would prefer to keep confidential. Industry trade associations may be able to establish "third-party" mechanisms whereby individual manufacturers can enroll their products in appropriate groups while minimizing the extent to which confidential data must be revealed. Each producer will need to determine whether the cost-sharing advantages provided by group participation outweigh the possible competitive risks involved. However, whether a manufacturer chooses to participate in group functions or to satisfy the registration requirements through independent testing, section 211(b)(2) stipulates that "the results of such tests shall not be considered confidential".

2. Cost-Sharing Provisions

The main purpose of the proposed grouping system is to apply section 211(e)(3)(B), which permits producers who manufacture or process the same fuel or fuel additive to share the responsibilities of the program so that requirements can be met without duplication of cost and effort. EPA has had extensive experience with cost-shared testing conducted by manufacturers in compliance with regulations under TSCA Section 4. To date, EPA has found the persons conducting tests under Section 4 have chosen in each instance to work out their own arrangements for cost-sharing or reimbursement without any need for EPA involvement. While formal data reimbursement regulations were issued for this purpose in 40 CFR part 791, no one has yet invoked the procedures therein.

EPA believes that a similar result would be likely if cost-sharing rules were promulgated within the fuels and fuel additives registration program. At this time, therefore, EPA proposes to leave the development of specific cost-sharing agreements up to the participating manufacturers. However, comments are solicited concerning the potential need for EPA involvement in these arrangements. If such involvement is deemed necessary, opinions are requested on the adequacy of existing TSCA regulations for this purpose or an alternative cost-sharing guidelines or procedures.

One possibility under consideration would require manufacturers of existing fuels and fuel additives to notify EPA within one year after publication of the final rule if they intended to comply with the rule as part of a group and, if so, to identify the person or entity which was organizing the testing. For new fuels and fuel additives, manufacturers would be required to conduct the testing individually unless they first certified to EPA that they intended to rely on data previously submitted by a manufacturer of a similar product. The certification would need to include assurances that the first manufacturer had been notified of this intent and that the first manufacturer has the right to reimbursement under procedures such as those specified at 40 CFR part 791. Comments on these possible mechanisms are requested.

Arrangements for cost-sharing will need to account for two general situations. In one case, groups of producers would organize prospectively to complete the same program requirements for their similar products. In this instance, cost-sharing arrangements could be reached in advance of testing. Such arrangements might divide the program costs on a per-product basis or in proportion to applicable market share, sales revenue, production volume, and/or other relevant parameters which participating manufacturers agree would be equitable.

The second situation involves the case where adequate information already exists for the registration of a product because the required tests have been completed by another manufacturer (or group of manufacturers) on similar products (i.e., products meeting the criteria for membership in the same group as the new product). In this instance, the costs of program compliance would already have been incurred, and a manufacturer with a similar product wishes to reply on this existing testing in satisfaction of the registration requirements for his similar product. EPA proposes that, to use the existing test results, the new manufacturer would be required to notify the existing manufacturer that he has used the data and apprise him of his right to be reimbursed. EPA invites comments on whether these arrangements should be left to the producers to work out among themselves. Alternatively, EPA rules could be promulgated specifying the computation of reimbursement fees and the number of years that reimbursement rights would remain in effect. In that instance, EPA proposes that the "ownership" period for registration information should last for five years after data submission. To be reimbursed when new producers seek to rely on their existing data for fuel/additive registration, the original producers (or groups of producers) would be required to document the costs already incurred in conjunction with the registration program's information gathering and testing requirements. The level of reimbursement would be determined according to the applicable costs and the number of producers relying on the information for registration purposes. Comments are requested about the suitability of these or other alternative reimbursement arrangements.

V. Emission Generation

As discussed in section III.E, the proposed requirements for evaluating the potential emissions-based health and welfare effects of fuels and fuel additives include analytic procedures in Tier 1 for characterizing the chemical composition of fuel/additive emission products, as well as biological studies in Tiers 2 and 3 involving the exposure of laboratory animals to fuel/additive emissions. This section presents the methods proposed for generating, storing, and sampling the emissions to be used in these chemical and biological tests. With a few noted exceptions, emissions will be generated according to the Federal Test Procedures (FTP) for light-duty vehicles (40 CFR part 86).

A. Vehicle Requirements

1. Vehicle Selection

Because the composition of emissions produced by a given fuel or additive is likely to vary somewhat depending on the vehicle involved, a fully comprehensive testing program would need to encompass the emissions from many vehicles representing a complete cross section of the in-use fleet. In the context of the proposed Reformulated Gasoline Rulemaking, EPA suggested that to obtain a statistically significant set of emission characterization results encompassing the variety of emission control systems available, emissions would need to be generated from at least 20 vehicles for each fuel under evaluation (see Supplemental Notice of Proposed Rulemaking, available in Docket # A 91 02). For purposes of the routine registration of motor vehicle fuels and fuel additives, however, EPA believes that such an extensive emission sampling and testing scheme may not be reasonable or necessary. EPA is initially proposing that only one vehicle be required to generate the emissions to be used for the chemical and biological testing included in Tiers 1 and 2, while potential Tier 3 requirements might call for the use of additional vehicles. Alternatives to this basic proposal are discussed later in this section.

Similar to the reformulated gasoline proposal, the parameters to be considered in specifying the vehicles to be used for emission generation include vehicle class, emission control equipment, and vehicle sales volume. First, for each fuel family, the vehicle class and subclass to be used for emission generation will be that which reflects the highest yearly amount of consumption of fuels in that family. Normally, vehicle classes include light-duty vehicles (LDV), light-duty trucks (LDT), and heavy-duty vehicles/engines. For purposes of this program, however, EPA proposes that LDV and LDT be combined into one vehicle class. LDT represent a large fraction of the gasoline fuel consumed in the U.S., but less than the fraction attributable to LDV. Thus, if LDV and LDT are maintained in separate classes, LDT would probably not be selected for generating emissions from gasoline fuels and fuel additives. Although LDV and LDT are expected to

produce similar emissions, reflecting the fact that their engines, emission control systems, and emission standards are similar, the absence of LDT in the program might still reduce the representativeness of the test emissions for gasoline fuels and fuel additives. Comment on whether or not LDV and LDT should be combined into one vehicle class would be appreciated.

In view of the overwhelming proportion of total diesel vehicle miles which are traveled by heavy-duty diesel vehicles, heavy-duty engines are expected to be used to generate test emissions for diesel fuels and fuel additives. Because of the lack of heavy-duty vehicle testing facilities, however, emission generation using light-duty vehicles of the same fuel class may be preferable from the standpoint of practicality. Comments are requested on this issue.

The next step is to determine the selection criteria for specific vehicle models. The vehicles to be used for emission characterization must be new vehicles of the model year in which testing begins. However, vehicle selection criteria are to be based on technology characteristics of the previous model year. The group or company seeking registration would first determine the most common fuel system and emission control system combination in the applicable vehicle class. The criteria to be considered for light-duty gasoline powered vehicles, for example, might be fuel metering approach (carburetted, fuel injected (port, throttle body) and emission control approach (catalyst type, air injection, exhaust gas recirculation (EGR), feedback control, etc.). The company could then select for testing any one of the top five selling models with these characteristics, based on the previous model year's sales. If any of the five selected models were not available in the model year when the new vehicle was to be purchased for testing, the selection would be limited to the models remaining.

In general, the vehicle selection criteria described above would be used to determine the representative vehicles for all fuel families. However, fewer than five vehicle models may be available for "alternative" fuel families. In such instances, any available model could be used for testing. The proposed vehicle selection procedure is more thoroughly described and illustrated in a memorandum entitled, "Vehicle Selection Procedures for the Proposed Fuels and Fuel Additives Rulemaking," available in the public docket.

Comment is requested on how to determine the types of vehicles that should be used to test fuels and additives which are not commonly used or intended to be used in the vehicle type which the standard vehicle selection procedure would prescribe. This situation might arise, for example, in the selection of vehicles for testing lead substitute aftermarket additives (which may damage vehicle catalysts) and for testing number 1 diesel fuel (most commonly used in urban buses).

2. Mileage Accumulation Requirements

Mileage accumulation is important for this program for two primary reasons: It "breaks in" a new vehicle so that the emissions stabilize (an effect which is independent of the fuel used in the vehicle) and it allows potential long-term effects of the fuel or additive on emissions to be assessed. Suggestions for the amount of mileage accumulation appropriate for this program have varied. Some have suggested that the minimum mileage needed to "break in" a new vehicle (approximately 4,000 miles for light-duty vehicles) would be sufficient for this program, claiming that the fuels used in the vehicle do not drastically affect the emissions of a vehicle. Others have suggested that emission characterization be continued throughout the useful life mileage of the vehicle (50,000 miles for light-duty vehicles, changing to 100,000 miles in 1994) in order to determine the full effects of the fuel or additive being tested. Another advantage gained by requiring a significant amount of mileage accumulation is that it reduces the chance of "gaming" the test results by discouraging the testing of a number of vehicles and selection of the best results. Therefore, EPA proposes 25,000 miles as the minimum mileage which must be accumulated using the subject fuel or additive/base fuel mixture before testing is conducted. This value reflects a point between the two positions that provides a reasonable opportunity for long-term effects of the fuel or additive to be revealed, while at the same time avoids undue burden. As will be discussed further below in sections V.D and VI.A.2.f, additional mileage may be necessary for fuels and additives containing atypical elements. Comment with supporting data is requested regarding the appropriate mileage accumulation requirements for vehicles used in the testing of baseline/non-baseline and atypical formulations.

The proposed mileage accumulation would be required to begin when the vehicle was new, using only the fuel or additive/base fuel mixture of interest. Mileage could be accumulated by any appropriate means. For example, the vehicle could be placed in the company's fleet, held for controlled fleet use, or driven on the street, test track, or dynamometer solely for the purpose of mileage accumulation. Vehicles would be required to be unmodified and maintained as instructed in the vehicle owner's manual.

3. Alternative Approaches

As stated earlier, a comprehensive determination of the emissions from a fuel or additive could require testing the emissions from at least 20 vehicles, and EPA request comment on whether testing emissions generated by only one vehicle is sufficient to screen for representative emission compounds and their related biological effects in this program. EPA is considering a compromise between testing one vehicle and testing 20 vehicles, in which perhaps three to six vehicles, representing differing emission control technologies, would be used to generate emissions for emission characterization purposes. One of these vehicles, or perhaps a combination thereof, would be chosen to generate emissions for biological testing.

Another possible variation in the proposal would allow in-use vehicles which have already accumulated sufficient mileage to be employed for generating emissions instead of requiring mileage accumulation on new vehicles. While this alternative would reduce compliance costs, it has some possible drawbacks. Long-term emission effects caused by the fuels and additives previously used in these vehicles could alter the generated emissions and therefore the emission characterization and biological test results. It would then be difficult to assess the extent to which the test fuel was responsible for the test results. Another drawback is the absence of information on the long-term effects of the test fuel or additive. Finally, gaming could occur such that emmission characterization could be performed on many vehicles and only the best results submitted. Comment is requested on whether in-use vehicles would be acceptable for this program.

EPA has also identified an alternative emission generation scenario which incorporates a number of the possible program modifications described above. Because this scenario would require the use of more vehicles in the testing program in order to increase the confidence that can be placed in the results, methods of reducing other associated costs have also been identified.

First, with regard to fuels and additives that do not contain an atypical element (i.e., those in the baseline and

non-baseline formulation classes), the required number of vehicles would be increased from one to six. The vehicle selection criteria would include the same emission control system characteristics as described previously, except that six technology groups would be determined from the emission control system combinations, and the top seller from each group would be included in the program.

To reduce costs, mileage accumulation requirements per vehicle would be reduced, perhaps to the 4,000–10,000 mile range. The use of new vehicles would be encouraged, but in-use vehicles would be permitted after specified intermediate preconditioning, assuming that the fuel or additive producer was willing to accept the program outcome risk of using vehicles which had been operated on other fuels and additives.

A prime tenet of this approach is that emissions carryover from the use of one fuel or additive to another in the same vehicle can be eliminated by an intermediate preconditioning process. This would permit one vehicle to be used to generate emissions for more than one product. One potentially applicable intermediate preconditioning method has been used in the Joint Auto/Oil Air Quality Improvement Program. Additional discussion on preconditioning methods is available in a memorandum in the public docket. EPA asks for comment on the validity of the assumption that fuel emission carryover effects can be eliminated with a reasonable amount of intermediate preconditioning.

A valid preconditioning process would not only permit previously used vehicles to be employed in the testing program, but would also allow the same vehicles to be used for testing more than one product. For example, the proposed testing of fuel additives requires the emissions of an additive/base fuel mixture to be compared with the emissions of the base fuel alone. This could be accomplished by performing one set of emission characterization control tests on the base fuel in each of the six vehicles. Then, with intermediate preconditioning, the same set of six test vehicles could be used to perform emission characterization for any number of fuel additives in the same fuel family, excluding those with "atypical" elements. In this way, only one set of base fuel emission characterization results would suffice for all products that underwent testing using the same set of vehicles.

Specific fuel formulations subject to testing would also be required to undergo emission characterization using six vehicles. Comment is requested as to whether producers testing these specific formulations should, for comparison purposes, also be required to test the applicable base fuel using the same six test vehicles (assuming that the fuel being tested is not itself a base fuel). Under this scenario the incremental expense would be expected to be small. As was mentioned above, a specified intermediate preconditioning cycle would have to be performed at the time the vehicle is switched between different fuels, additive/base fuel mixtures, or the base fuel.

Once the emission characterization was complete, one of the same six test vehicles would be selected and used to generate emissions for biological testing. The selection of this vehicle would be based on analysis of the emission characterization data. A number of alternative selection criteria are possible. For example, the vehicle could be chosen to represent either the average or highest emission rate of volatile organic compounds, total toxicants, particulate matter, and/or PAH. EPA would appreciate comment on the parameters that should be used to select the vehicle to be used for emission generation for biological testing. Another possibility would be to use all six vehicles, with each vehicle generating emissions for one-sixth of the testing time period.

For fuels and additives in the atypical formulation class, the atypical elements potentially have a much greater chance of affecting the vehicles' emission control components, making long-term emission effects much more likely. Thus longer mileage accumulation to steady state may be necessary. Furthermore, multiple use of vehicles may not be possible because the intermediate preconditioning process may not be effective at eliminating potential carryover effects of the atypical elements. To increase confidence in the results of the testing, six vehicles selected as described above would be required to accumulate mileage. In order to isolate long-term effects, EPA proposes to require the use of new vehicles, but asks for comment on whether low mileage used vehicles would be an acceptable alternative. Emissions from all of the test vehicles would be characterized, and these results would be compared with the baseline group representative of that fuel class (see section V.E.2).

Finally, two alternatives have been identified for conducting biological testing on group representatives in the atypical formulation class. Under the first alternative, only one of the vehicles would be chosen to undergo further mileage accumulation to reach steady state (e.g., the vehicle with the highest atypical element emission rate of the six vehicles). Then, speciation of the emissions containing atypical elements and the required biological tests would be performed. Under the second alternative, all of the vehicles would need to reach steady state. Speciation of the atypical emissions would then be done for all six vehicles. Biological testing could be done either on one selected vehicle, or each vehicle share in the emission generation for biological testing (as was discussed above for the baseline and non-baseline formulation classes). EPA solicits comments on these scenarios designed to cost-effectively generate the data required by the statute.

B. Combustion Emission Generation

The FTP through the exhaust emissions test is the method proposed for generating the combustion emissions needed to meet the emission characterization requirements of Tier 1. These procedures are specified in 40 CFR part 86 for the certification of new motor vehicles, and may vary depending on the fuel family and vehicle class.

Consistent with the current FTP requirements, canister loading during the FTP preconditioning phase must be done by methods that use actual evaporative emissions rather than bench methods, which use a surrogate compound for canister loading. This will help to ensure that emissions are generated exclusively from the fuel or additive being tested. Modifications to the standard FTP will be needed to collect particulate and semi-violatile emissions, which are required both for emission characterization and in vitro biological testing. The particulate fraction is to be collected on filters and the semi-volatile emissions collected immediately downstream from these filters, using porous polymer beds or other equipment designed for their capture.

After collection, the organic fraction of the particulate and semi-volatile emissions would be extracted separately from each other using appropriate laboratory procedures. Because the extracted materials would be much more stable than gaseous combustion emissions, they could be stored for longer periods of time before use. For this reason, the particulate and semi-volatile emissions could be generated and used in different locations, as long as proper handling techniques were observed.

For in vitro biological testing purposes, the particulate emissions may

be collected on a single filter instead of on multiple filters as prescribed in the FTP. Similarly, semi-volatile phase emissions may be collected on one apparatus for the entire driving cycle. If an insufficient amount of particulate or semi-volatile material is obtained during a single driving cycle, the FTP may be repeated as required and the extracted organic fractions combined.

Many of the in vivo biological tests proposed in today's notice would require six weeks exposures of laboratory animals to whole combustion emissions for a minimum of six to eight hours per day. The continuous generation of emissions throughout the required exposure periods requires light-duty vehicles to be driven through repeated Urban Dynamometer Driving Schedule (UDDS) driving cycles and heavy-duty engines to be operated over repeated Engine Dynamometer Schedule (EDS) cycles (40 CFR part 86, appendix I), with emissions diluted and routed directly from the vehicle to the biological testing chamber. Provisions in the proposed regulations allow for a limited amount of emission generation disruption without voiding the biological test.

The use of automated systems may provide a means to reduce the difficulties associated with continuous emission generation. Automated systems would involve computerized mechanisms used to drive the vehicle on a chassis dynamometer or an engine on an engine dynamometer. These systems could be used in place of human operators to perform the monotonous task of performing repeated driving cycles. Throttle actuators linked to a computer system along with electric chassis dynamometers could be programmed to drive vehicles over driving cycles. Such systems have been used in the past for mileage accumulation purposes and for assembly line vehicle testing. However, their application is limited to vehicles equipped with automatic transmissions.

Robotic drivers are fairly recent options for automated vehicle operation, and are expected to provide high repeatability and versatility. The technology for these systems has been developed for related applications, but has not been widely used thus far.

A third possibility for automation would involve the use of an isolated engine (in conjunction, perhaps, with the vehicle's fuel and emission control systems) attached to an engine dynamometer. Since the input parameters required for controlling engine dynamometers are different from the wheel speed driving trace of the chassis dynamometer, the light-duty Urban Dynamometer Driving Cycle would need to be translated to an equivalent load-speed pattern, or else an alternate driving cycle would be required.

EPA is initially proposing to require the use of engine dynamometers to generate emissions for the heavy-duty class and chassis dynamometers to generate emissions from light-duty vehicles. In the heavy-duty case, use of an engine dynamometer for emission generation is consistent with all existing heavy duty emission testing programs and also provides considerable cost advantages. In contrast, in the light-duty case, existing emission testing programs require the use of a vehicle operated on a chassis dynamometer for emission generation. To use an engine dynamometer for this purpose, extensive testing would have to be done to demonstrate that the exhaust emissions were the same as those generated from the corresponding light-duty vehicle operated on a chassis dynamometer. Many technical problems would have to be confronted in attempting to isolate the engine and emission control equipment from the vehicle while assuring that the representativeness of the emissions would be maintained. These would include decisions on which vehicle systems must remain attached to the engine and what methods to use to terminate unnecessary systems; the addition of a flywheel, harmonic balancer, and bell housing to balance the system for vehicles equipped with automatic transmissions; determination of the effect of detaching transmission sensors such as gear sensors, clutch lock/unlock sensors, and torque coverter speed sensors; and the translation of the LA–4 chassis dynamometer driving cycle to an operating cycle appropriate for use with an engine dynamometer.

EPA believes that the putative cost savings associated with the use of a light-duty engine dynamometer rather than a light-duty vehicle and chassis dynamometer would be overridden by the costs associated with resolving these problems and performing tests to prove that the solutions were valid. However, EPA is open to comment on the relative costs and benefits of the light-duty chassis dynamometer vs. engine dynamometer, and would consider making the use of the engine dynamometer optional in this program if the comments provide persuasive evidence that this option would be advantageous.

C. Evaporative Emission Generation

As discussed above the section III.C, the evaporative emissions of some fuels and additives will be required to undergo emission characterization and biological testing. The composition of evaporative emissions does not, in general, resemble fully-evaporated whole samples of raw fuels or fuel additives due to differences in vapor pressure of the fuel or additive components and the effects of evaporative emission control equipment. The largest sources of evaporative emissions from vehicles are diurnal, hot soak, and running loss emissions. For the purpose of this rulemaking, refueling emissions are also regarded as evaporative emissions due to their generally similar composition. While the most technically accurate method of testing these emissions would be to characterize and perform biological tests on each evaporative source separately, such a plan would multiply the costs involved. The proposed evaporative emission characterization requires call for the speciation of emissions from all types of evaporative emissions measured in the FTP effective at the time the testing is done. EPA asks for comments on which types of evaporative emissions should be speciated and if the program should be expanded to include running losses and refueling emissions.

EPA is also proposing that evaporative emissions be generated without using key components of evaporative emission control systems, such as the carbon adsorption canister. An intact control system would represent normal system design, and removal of the canister would change the relative concentrations of the evaporative emission products. On the other hand, disconnecting the evaporative emission control system would provide the opportunity to examine emissions simulating uncontrolled emission sources such as refueling operations and leaky evaporative emission control systems. Furthermore, as discussed below, use of emission control may not be practical for evaporative emission generation for biological testing purposes. If the emission characterization procedures are to be performed on emissions that closely resemble those used for biological testing, it may thus be necessary to disconnect the emission control system when generating emissions for speciation purposes, as well.

Three simplified procedures are being considered for continuously generating evaporative emissions for in vivo biological testing. The first would require that evaporative emission generation be performed by using a

sealed housing for evaporative determination (SHED). The diurnal heat build section of the FTP would be performed, and samples of the vapors in the SHED would be withdrawn into Tedlar bags and used for testing. Chemical artifacts caused by storage of evaporative emissions are expected to be much less of a problem than for combustion emissions. For this purpose, the SHED would need to be equipped with a sampling port and sampling pump. To avoid modification of the sample, a pump with low hydrocarbon absorption and emission characteristics (e.g., a teflon diaphragm pump) would be required. Generating evaporative emissions without any of the key emission control system components in place would help increase the concentration of evaporative emissions in the SHED in order to produce a sample useful for biological testing. However, the concentration of evaporative emissions in the SHED might still be too low to be useful for biological testing purposes, even if the evaporative emission canister were disconnected.

Another alternative would use evaporative emission speciation data to make a surrogate mixture of adequate concentration for biological testing. While this method might seem to have some practical advantages, it would rely heavily on the speciation data as a complete and accurate representation of in-use evaporative emissions.

The third method for generating evaporative emissions would be an evaporative emission generation chamber instead of a vehicle. The chamber would be temperature and pressure controlled so that its characteristics were similar to the head space of the fuel tank of a vehicle where in-use diurnal and refueling emissions are generated. The chamber would be 40 percent filled with the fuel or additive/base fuel mixture, and the remainder filled with air. The system would be heated to a prescribed level and the fuel or additive mixture allowed to evaporate. When equilibrium was reached between the fuel in the liquid and vapor states, the vapor and air mixture would be withdrawn for dilution and testing. The fuel or additive/base fuel mixture would need to be renewed periodically to keep the emissions of constant character.

An extension of this concept would involve the construction of a bench apparatus using a duplicate of the fuel tank of the vehicle involved together with heating elements. Vapors could then be drawn directly from the head space of the fuel tank. However, this method might create safety concerns concerning the heating of the sample to cause evaporation. One option would be to reduce the air pressure over the fuel or additive/base fuel mixture to induce evaporation.

In comparison with the SHED-based system, the bench method has the advantage of requiring much smaller, less expensive, and simpler equipment. Emissions could be generated close to the biological testing chambers, and largely automated systems could be used. Another advantage is that the concentration of emissions which occurs in the biological test chamber could be controlled to a much greater extent with bench methods than with the SHED method, in which air dilution is fixed by the size of the SHED and the specific vehicle generating the emissions. The surrogate emission generation method has the drawback of relying too heavily on the speciation data for its accuracy. For these reasons EPA proposes to require the use of a bench method (i.e., evaporation chambers) for generating emissions for in vivo biological testing. Comments are requested on this issue.

EPA proposes that evaporative emission control equipment not be used on the emissions generated by the evaporation chamber. As stated above, this would enable the testing of emissions which represent uncontrolled emission sources such as refueling operations. In addition, removal of the emission control canister would allow the generation of more concentrated emissions, which are required for the biological tests specified under Tier 2 of this program. A third reason is the complexity of the procedures which would be required for canister loading and purging cycles if the emissions from the evaporation chamber were to resemble in-use vehicle evaporative emissions. EPA requests comment on this question of the proper use of evaporative emission control systems for biological testing purposes.

EPA is aware that the methods proposed are different for combustion and evaporative emissions with respect to the role of emission control equipment. This inconsistency arises from practical considerations. First, in the case of combustion emission control, many different vehicle components are involved. While some of these components could possibly be removed or disabled to simulate emission control malfunction, others are integral to proper running of the engine and their removal would cause the vehicle to be inoperable. Therefore, generating totally uncontrolled combustion emissions would not be a reasonable option. Secondly, the types of combustion emission control equipment and each component's individual effects on emissions varies greatly from vehicle to vehicle, making it extremely difficult to devise a reasonable basis for determining which components could selectively be disabled. Thus, all combustion emissions control components are proposed to be maintained in the proper functioning condition during combustion emission generation for this program.

Conversely, at the present time, the primary (vehicle-based) source of evaporative emission control is the evaporative emission canister. This device does not affect a vehicle's operability. In order to obtain evaporative emission samples of sufficient concentration for biological tests, and to represent uncontrolled emissions sources, EPA has proposed that evaporative emission control equipment be disconnected for evaporative emission generation.

Comments are requested on whether a consistent use of emission control equipment for combustion and evaporative emissions is important for this program, and if so, how the program should be restructured to accomplish this end. If the program were restructured, EPA specifically asks for comment on the desirability of using a controlled evaporative system for emission characterization purposes and an uncontrolled system for biological testing.

D. Additional Emission Generation Topics

1. Emissions for Atypical Elements

The "atypical" elements described in section IV (generally, those other than carbon, hydrogen, oxygen, nitrogen, and a limited amount of sulfur) may form particulate combustion products which can deposit on the inside of the vehicle's engine or emission control system. Deposition of the atypical elements inside the vehicle may be particularly significant when the fuel or fuel additive is first introduced, thus interfering with identification and accurate measurement of the atypical species. As the internal deposits increase, it is expected that a greater fraction will be emitted into the atmosphere until the net deposition inside the vehicle/engine is small.

As is discussed further in section VI.A.2.f below, additional requirements are thus proposed for "atypical" fuels and additives to ensure that the atypical elements are fully represented in the sampled emissions. After the minimum

25,000 miles have been accumulated, emissions will be collected from the vehicle and subjected to preliminary analysis, including the standard characterization required for all fuel and additive formulations and those which measure the presence of atypical elements in exhaust and, if applicable, evaporative emissions. Then, measurements will be made to determine whether a steady state has been reached between the rate of entry and emission of the atypical elements. If not, additional mileage accumulation will be performed until the emissions of the atypical elements reach steady state. Steady state will be defined as the point at which the mass of the atypical elements emitted during the performance of one or more Urban Dynamometer Driving Schedules/Engine Dynamometer Schedules is within 10 percent of the mass of the atypical elements that entered the combustion chamber during the driving cycles.

In determining whether steady state has been reached, some less obvious pathways for the loss or introduction of the atypical elements may need to be taken into account. For example, if the atypical compounds could be lost through evaporation, then the evaporative emissions would be speciated for these compounds. If the atypical element enters the motor oil via the combustion chamber, the concentration of the atypical element in the motor oil may be measured and entered into the mass balance. If there is reason to suspect that the air used during combustion or dilution may contain significant quantities of the atypical element under evaluation, this air must also be tested and the problem rectified.

EPA is initially proposing that mileage accumulation be continued either until steady state of the atypical elements has been reached or until the vehicle or engine has been operated on the atypical fuel or additive for the equivalent of 80 percent of its estimated useful life (e.g., 80,000 miles for light-duty vehicles). The purpose of this rigorous requirement is to ensure that the emission products of the elements of concern are known and that their concentrations are stable when the emissions are used in subsequent testing. In actual use, however, few vehicles are likely to be driven continuously on "atypical" fuels and additives. The use of such products by consumers is more likely to be intermittent and/or limited to particular owners along the chain of individuals who may own a given vehicle. Thus, the proposed requirement for accumulating mileage up to 80 percent of a vehicle's or engine's useful life (unless steady state is reached at an earlier point) may far exceed the amount of mileage and the concentration of atypical emission products which would generally be encountered in actual use. If so, a lower mileage requirement, perhaps in the range of 25–50 percent of the vehicle's useful life, may be more appropriate in pursuit of the steady state condition. Comments are requested on these issues and on appropriate mileage accumulation requirements. Data on typical consumer usage patterns for atypical products would be particularly helpful to this decision. If the comments are supportive of a change in the proposed requirements, EPA would expect to reduce the mileage accumulation required in the Final Rule for atypical fuels and additives to a mileage figure in the lower range mentioned above.

2. Verification Testing

A number of mechanisms can cause emissions to be captured in the dilution and sampling system before they can be characterized or used for animal exposures. The ratio of emissions that exit the sampling system to those that enter is called the "recovery factor" of the system. The recovery factor must be high in order for subsequent emission testing to be meaningful. Determination of the recovery factor is called verification testing.

Verification testing is required in the FTP using propane or carbon monoxide for gasoline and diesel fuels and using methanol for methanol-containing fuels. It is accomplished by injecting a known sample into the dilution system at the end of the exhaust pipe and measuring the amount that exits the sample probe. While the performance of this standard verification testing will determine if the system is leaking, recovery of these compounds does not necessarily imply the recovery of all of the different compounds subject to the speciation procedures of this program or all biologically significant emission products. EPA asks for comment on whether further verification testing should be required for this program using additional compounds.

In order for the system to be acceptable, a minimum recovery rate would be required for each compound in an injected sample composed of known chemicals of the type under analysis. Such verification procedures would be relatively easy to perform when emissions are being generated for characterization purposes, since calibration compounds and speciation equipment would be readily available. However, when emissions are being generated for purposes of biological testing, simplified verification testing may be in order, since biological testing laboratories may not always have sophisticated speciation apparatus available. In this case, an injected hydrocarbon sample could be detected with a gas chromatograph and flame ionization detector to estimate the recovery factor. EPA asks for comment on these proposed requirements for verification testing.

3. Emission Storage and Transport

As mentioned previously, emissions can be stored for only a limited period of time before chemical changes may occur. The critical time period is a function of the composition of the emissions, the temperature and pressure under which they are contained, the vessel in which they are stored, the amount of sunlight to which they are exposed, and the amount of deterioration that is considered acceptable. The maximum allowable storage times for emissions which are to be subjected to chemical analysis will vary depending on the speciation protocol, and are identified in relevant parts of the proposed regulatory text.

Storage time is not an issue in regard to biological tests using whole combustion or evaporative emissions, since these emissions are to be generated continuously. Particulate phase emissions can be stored up to six months, either on the collection filter or after extraction. The stored material must be sealed in a container that is opaque to ultraviolet light and maintained at −200 C or less. Semi-volatile phase emissions must be extracted immediately after collection, stored at −200 C, and used within six months. Special emission handling specifications for biological testing purposes are considered in section VI.C. Comments on these storage and handling specifications would be welcome.

4. Emission Generation Facilities for Biological Testing

While the continuous generation of combustion emissions appears to be an essential component of the proposed *in vivo* biological test requirements, EPA is unaware of any commercial biological laboratories which offer such services at the current time. Installation of the necessary vehicle-related equipment by biological laboratories would require significant capital expenditure and considerable time for start-up and training. Similar problems would arise if vehicle testing labs were to install

biological exposure chambers adequate for the proposed program. EPA asks for comment on the ways in which adequate facilities for the biological testing required by this program can be made available to the fuel/additive producers seeking registration, either through increased facility availability or simplified testing requirements. EPA also asks for comments and suggestions on what remedies are available under the Act if adequate facilities have not become available when testing is to be conducted.

E. Special Requirements for Additives

1. Base Fuel Specifications

As discussed in Section III, fuel additives subject to testing are to be mixed with the designated base fuel formulation for their respective fuel family prior to the generation of emissions. The base fuel formulations are also proposed to serve as the representatives for groups in the baseline fuel/additive categories. To define appropriate base fuel formulations for the gasoline, diesel, and methanol fuel families, EPA proposes to establish specifications based on the national annual average of fuel sales. For this purpose, EPA plans to adopt the method proposed in the reformulated gasoline rulemaking (56 FR 31176), which uses sales-weighted averages of fuel survey data to determine national average parameters for wintertime unleaded gasoline. The averaging procedure will be based at least in part on Motor Vehicle Manufacturers Association (MVMA) fuel survey data.

In the near future, "alternative" fuels are expected to generate demand for a variety of new bulk and aftermarket fuel additives. At the present time, however, base formulations for these alternative fuel families will not be defined. When the time comes that a fuel additive to an alternative fuel requires a base fuel for testing purposes, an industry average of important parameters in existing fuels will be determined and the base fuel specification defined.

Fuel additives will need to be added to the "average" fuels determined by the survey in order for these fuels to be used in motor vehicles. Examples of necessary fuel additives may be stabilizers, deposit control additives, and corrosion inhibitors. Only additives determined to be necessary for proper fuel and vehicle functioning will be components of the base fuels. These additives, along with their in-use concentrations, will be determined by EPA with input from interested industries and groups.

A memorandum entitled, "Base Fuel Determination Procedures for the Proposed Fuels and Fuel Additives Rulemaking," is available in the public docket. This memorandum illustrates the proposed approach for specifying base fuel formulations and presents sample values for base gasoline and diesel fuels. It also discusses such issues as base fuel blending tolerances and the need for a standard set of base fuel additives.

2. Additive and Base Fuel Emissions Comparison

Emissions from fuel additives may, in some cases, be difficult to distinguish from the emissions of the base fuel itself. Ideally, the emissions contributed by an additive would be determined by performing tests on two identical vehicles, one fueled with the base fuel alone and the other fueled with the additive/base fuel mixture. Test results on the emissions from the two vehicles would be compared and the difference attributed to the fuel additive. However, significant variability can exist between vehicles even of the same year and model. Furthermore, the additional expenditure for conducting tests on two vehicles, one with and one without the fuel additive, would be considerable. Nonetheless, from a scientific perspective, side-by-side testing would be the preferred approach.

An alternative to this method is proposed, in which only one vehicle model would generate and test the base fuel emissions for each fuel family, with the results made available for use as control data for all additives in the fuel family. Standardization of the vehicle make, model, and year would be an important requirement. Under this approach, base fuel testing would be done as part of the program automatically, since the group representative for each baseline group is also a base fuel for the respective fuel family. Thus, no additional effort would be required on the part of the additive producers in order to perform the comparison analysis. This method could provide a reasonable set of control data for comparison against the test results for fuel additives (both emission characterization and biological studies), at a fraction of the cost of the more rigorous approach. However, the requirement that the same vehicle make, model, and model year be used for testing the base fuel and the additive/base fuel mixture would become problematic for fuel additives tested some years after the base fuel was tested, since acquiring a new (unused) vehicle of a previous model year would be difficult. EPA asks for suggestions as to how this requirement can be effectively implemented. Of course, any additive producer could conduct independent base fuel testing in lieu of relying on the results of the group responsible for base fuel testing.

In case the baseline group(s) in some fuel families are able to satisfy the Tier 1 and Tier 2 requirements based on existing testing, EPA asks for comment on how various additive producers needing base fuel information could work cooperatively for these purposes. EPA also requests comment on the appropriateness of this proposed method for distinguishing the emissions effects of fuel additives from the emission effects of the base fuel.

Section V.A presented another alternative for comment, in which six vehicles would be used to generate emissions both for the additive/base fuel mixtures being tested and for the applicable base fuel. While this approach would reduce the problem of vehicle-to-vehicle emissions variability, it depends on the validity of the assumption that carryover effects from fuels and additives used previously in the vehicles would be negligible. To the degree that this assumption is valid, the use of the same vehicles to generate emissions for comparison might be preferred.

3. Additive Concentration

Prior to emission generation and testing, additives are to be mixed with their associated base fuel to a concentration equal to that recommended by the additive producer as the maximum in-use concentration. One alternative would require mixing of fuel additives in their base fuels at a significantly higher concentration than the recommended amount, i.e., to "dope" the mixture with the fuel additive. Another possible method of doping an additive/base fuel mixture would be to significantly increase the concentration of particular components of an additive product (e.g., the compounds that contain atypical elements). The primary purpose of these approaches would be to enhance the contribution of the additive product (or the particular component of concern) to the emissions produced by the additive/base fuel mixture. This would facilitate the task of detecting and analyzing the additive's emissions and distinguishing them from the emissions produced by the base fuel. It would also effectively increase the dosage of additive emissions during biological exposures to additive/base fuel emissions, increasing the likelihood that observable changes could be detected in comparison with exposures

to emissions of the base fuel alone. EPA asks for comment on the mixing rules that should be adopted and on the validity of doping the base fuel with the fuel additive or active ingredient. Comment is also requested on appropriate additive concentration levels, if a doping procedure were to be adopted for the final rule.

VI. Evaluation of Health and Welfare Effects

The scope and general structure of proposed provisions for evaluating the potential health and welfare effects of fuels and fuel additives were discussed above in sections III.E and F. The program focuses on the contribution of fuels and additives to harmful air pollution, and includes requirements to determine the composition and potential effects of fuel/additive emissions generated by both combustion and evaporative processes. Health effects testing provisions are specifically focused on the effects of inhalation exposure to fuel/additive emissions in regard to the following selected endpoints: carcinogenicity, mutagenicity, developmental effects, reproductive effects, pulmonary toxicity, and neurotoxicity. The impacts of fuel and additive emissions on the public welfare and the environment are addressed by data research methodologies.

As previously described, the required evaluation procedures are organized within three successive tiers. All fuels and additives (or fuel/additive groups) must be evaluated in compliance with the first two tiers. Tier 1 includes requirements for the characterization of fuel or additive emissions, the compilation of existing information on the potential adverse effects of the emissions, and the modeling of exposure, reactivity, and environmental partitioning. Tier 2 is comprised of short-term biological screening tests for the specified endpoints. Both the Tier 1 emission characterization and the Tier 2 biological testing requirements may be mitigated by the demonstration of adequate existing testing. The information from these two tiers, together with other available toxicity and exposure data, will be assessed by EPA to determine when further study is needed to provide adequate information for regulatory decision-making. In that instance, additional testing requirements will be imposed under the provisions of Tier 3.

The specific requirements of each health/welfare evaluation tier are described in more detail in the following sections.

A. Tier 1: Characterization of Emissions

1. Scope of Characterization Requirements

The proposed requirements for emission characterization are intended to satisfy the provisions in Section 211 to "determine the emissions" of fuels and additives, and to provide a partial inventory of potentially harmful emission products for further study and evaluation in support of programs such as the Mobile Source Related Air Toxic Program (section 202(1)(l) of the Clean Air Act). In general, the required procedures are directed toward the detection and measurement of selected chemical classes and compounds. A complete and precise characterization of all emission products would require test protocols specific to all possible compounds, a nearly impossible task. For this reason, the proposed program focuses on measurement of regulated emissions and on the identification of specified classes of compounds of interest.

For most fuels and fuel additives, proposed emissions analysis requirements are limited to the determination of the emission rate of regulated emissions and the speciation of volatile hydrocarbons, aldehydes, ketones, ethers, alcohols, polycyclic aromatic hydrocarbons (PAH), (the subset of polycyclic organic material [POM] that includes only hydrocarbons) and nitrated polycyclic aromatic hydrocarbons (NPAH). These requirements are summarized in Figure 4. For fuels and additives that contain "atypical" elements (as defined in section IV), the chemical fate of the atypical components must be determined. Comments are solicited on the adequacy of these proposed areas of analysis for characterizing the emissions of fuels and fuel additives.

Comments are specifically requested on whether speciation of nitrogen-containing emissions should be included as a requirement for fuels and additives which contain appreciable quantities of this element. Such information might be of value in determining the chemical basis for toxic effects which might be observed during *in vivo* biological testing.

FIGURE 4.–EMISSION CHARACTERIZATION REQUIREMENTS

Emission type	RE	HC	Ket and Ald	Alc and Eth	PAH	NPAH
Combustion emissions:						
Vapor phase emissions	X	X	X	X [1]		
Semi-volatile phase emissions					X	X
Particulate phase emissions	X				X	X
Evaporative emissions: [2]						
Diurnal emissions	X	X		X [1]		
Hot soak emissions	X	X		X [1]		

[1] Required if alcohols or ethers exist in the uncombusted fuel.
[2] Only applicable to fuels/additives required to measure evaporative emissions RE=regulated emissions, HC=hydrocarbons, Ald and Ket=aldehydes and ketones Alc & Eth=alcohols and ethers, PAH=polycyclic aromatic hydrocarbons, NPAH=nitrated polycyclic aromatic hydrocarbons.

As proposed in section V, the generation of both combustion and evaporative emissions would generally involve equipment and procedures normally applicable to the certification of new vehicles. Three bags of vapor phase and three filters of particulate phase combustion emissions would be collected for each light-duty vehicle. For heavy-duty vehicles, one bag and one filter of combustion emissions would be collected during the cold start and one bag and one filter during the hot start segments of the transient test cycle. For fuels and additives subject to evaporative emission requirements, one bag of diurnal emissions and one bag of hot soak emissions would be collected from the SHED.

Unless otherwise noted, each speciation protocol is to be performed on each sample of combustion emissions. Speciation requirements for evaporative emissions are limited to the analysis of hydrocarbons, ethers, and alcohols (if the latter are present in the fuel/additive formulation). To provide an indication of the variability of emissions, EPA proposes that the entire

emission generation and characterization process be performed three times.

Collection and speciation of background samples is not required. However, if background samples are not speciated, the emissions that are measured in the speciation protocols will be assumed to be entirely due to the fuel or additive of interest.

2. Emission Characterization Protocols

The Clean Air Act authorizes EPA to require information to characterize fuel/additive emissions, while giving EPA discretion to specify the particular protocols which must be used for this purpose. Thus, the following sections identify the general emission product categories of interest and discuss currently available protocols which are suitable for these purposes. However, scientific methods can be expected to advance in the next few years, and the use of these protocols is not mandated. Rather, EPA will hold producers accountable for state-of-the-art methods and good analytical chemistry and laboratory practices. These practices are described in the article "Principle of Environmental Analysis", found in The Journal of Analytical Chemistry, 1983, Volume 55. The regulated emissions need to be measured by EPA approved methods. Current methods are described in 40 CFR 86; however, if these methods are revised or new compounds regulated, then methods in force at the time the regulated emissions testing is performed are the methods that must be used for this program.

a. *Characterization of regulated emissions.* The term "regulated emissions" for this program refers to emission products for which standards have been established for the purpose of the certification of new motor vehicles (40 CFR part 86). Vehicles of three fuel families (gasoline, diesel, and methanol) are presently required to undergo certification testing. The regulated emissions applicable to each family are shown in Figure 5. Oxides of nitrogen and carbon monoxide are regulated combustion emissions common to all three fuel families. Organic material is regulated in various forms depending on the vehicle and fuel type. Particulate emissions, already regulated for diesel cycle vehicles, will be regulated for light-duty Otto cycle vehicles beginning in 1994. Methanol-fueled vehicles are tested for methanol and formaldehyde as part of the organic material standards. Evaporative emissions from otto cycle vehicles and methanol-fueled vehicles are regulated for organic material, including methanol measurement when relevant.

FIGURE 5.—REGULATED EMISSIONS

Fuel cycle	Combustion emissions							Evaporative Emissions	
	Total HC	NMHC	OMHCE	OMNMHCE	NOx	CO	PM	Total HC	OMHCE
Gasoline/Otto	1	2			1	1	2	1	
Methanol/Otto			1	2	1	1	2		1
Diesel/Diesel	1	2			1	1	1		
Methanol/Diesel			1	2	1	1	1		1

Notes:
1 = Always.
2 = After 1994 for light-duty vehicles/trucks only.
Total HC = Total Hydrocarbons.
NMHC = Non-Methane Hydrocarbon.
OMHCE = Organic Material Hydrocarbon Equivalent (includes tests for HC, methanol, and formaldehyde).
OMNMHCE = Non-Methane OMHCE.
NOx = Oxides of Nitrogen.
CO = Carbon Monoxide.
PM = Particulate Matter.

The regulated emissions are to be measured for fuel/additive registration purposes in the same manner and with the same degree of accuracy as specified in 40 CFR part 86 for vehicle certification, including evaporative emissions and combustion emissions of both vaporous and particulate phases. Only those regulated emissions included in the certification requirements for the vehicle type and model year used to generate emissions for testing (selected according to the criteria in section V.A) need to be determined for this program. The results of these tests are to be reported in the manner specified for vehicle certification. Comments are requested on these requirements.

b. *Hydrocarbon characterization.* Speciation of hydrocarbons in the vapor phase of emissions is to be performed using methods that identity and determine the concentration of all hydrocarbon compounds containing twelve or fewer carbon atoms. An acceptable speciation method, available in docket A–90–07, is described in the document "Research Protocol Method for Analysis of Detailed Hydrocarbons Emitted from Automobiles by Gas Chromatograph" (June, 1991). The procedure is to be performed on both combustion and evaporative emissions. Hydrocarbon compounds of higher molecular weight (i.e., more than twelve carbon atoms) tend to condense and/or adsorb onto particulate surfaces at dilute exhaust temperatures and concentrations and are therefore not amenable to this type of analysis. EPA asks for comment on possible requirements for identifying chromatographic peaks using mass spectroscopy when peak identity is questionable and when coelution is suspected.

c. *Aldehyde and ketone characterization.* Speciation of aldehydes and ketones is required only for the vapor phase of combustion emissions, collected using the equipment and methods prescribed in 40 CFR part 86 for formaldehyde measurement. A currently available procedure which can accurately analyze aldehydes and ketones is the ASTM D5197–91, "Standard Test Method for Determination of Formaldehyde and Other Carbonyl Compounds in Air (Active Sampler Methodology)". The speciation procedure involves the reaction of aldehydes with 2,4-dinitrophenylhydrazine to form stable derivatives that are analyzed by high performance liquid chromatography (HPLC) using an ultraviolet light detector.

d. *Alcohol and ether characterization.* Alcohols and ethers are to be analyzed in combustion and evaporative emissions whenever the fuel or additive under evaluation or the base fuel mixed with the additive contains alcohols or ethers. The emissions are to be collected and analyzed using the procedures

prescribed in 40 CFR part 80, appendix F, entitled "Test Method for Determination of C1–C4 Alcohols and MTBE in Gasoline by Gas Chromatography". This procedure can be used for the identification of ethers in addition to MTBE, but will require appropriate modifications for application to gas phase samples.

e. *PAH and NPAH characterization.* PAH and NPAH are mutagenic compounds which have been designated as a topic for study by the Clean Air Act (section 202(1)(1)) to determine if their emission by motor vehicles should be regulated. PAH and NPAH are typically found in combustion emissions, and their identification in evaporative emissions will not be required under Tier 1 provisions. In the past, PAH and NPAH have been analyzed primarily in the particulate phase. However, evidence now suggests that the quantity of these compounds in the semi-volatile phase at the temperatures encountered in dilute exhaust may be important. For this reason, PAH and NPAH will be speciated in both semi-volatile and particulate phase emissions.

At this time, EPA is proposing that these PAH and NPAH characterization requirements be applied to all organic-based fuels and additives. However, it has been argued that the combustion of low molecular weight fuels such as methane, propane, ethanol, and methanol will not generate PAH and NPAH in significant quantities if the vehicles that generate the emissions are in proper operating condition. Comments and supporting data are thus requested on the necessity of imposing PAH and NPAH characterization requirements for these fuels.

Particulate and semi-volatile phase emissions are to be collected as specified in section V.B. The soluble organic fraction (SOF) is to be extracted from the filter and polymer bed separately and used in separate testing procedures. Protocols suitable for characterizing PAH and NPAH have been published by the Coordinating Research Council[4] Both methods 1 and 2 described for PAH speciation in this reference are acceptable, but the alternate method given for the detection of NPAH is not. EPA requests comments and suggestions regarding these proposed procedures.

f. *Characterization of emissions with atypical elements.* As discussed in section IV, fuels and fuel additives which contain chemical elements other than those included in the base fuel formulation for their respective fuel family are classified as "atypical" formulations. For the most part, atypical products are those with elemental components other than carbon, hydrogen, oxygen, nitrogen, and a limited amount of sulfur. Some of the atypical elements contained in such products are the following: Aluminum, Bismuth, Bromine, Cadmium, Cerium, Chlorine, Chromium, Cobalt, Copper, Fluorine, Iodine, Iron, Manganese, Molybdenum, Nickel, Lead, Platinum, Selenium, Sulfur (if present in amounts exceeding 1,000 ppm in gasoline formulations or 0.05 percent in diesel formulations), Titanium, Vanadium, Zirconium, and Zinc. In addition to the emission characterization requirements described in subsections a-e above, producers of "atypical" fuels and additives will be required to identify and measure the emission products containing the associated atypical elements. Because of the variety of potential elements and reaction products involved, all of the necessary chemical analytic procedures cannot be specified in this proposal. However, the procedures used must be state-of-the-art and based on sound analytical chemistry principles.

Generation of the emissions used for speciation of the emission products containing atypical elements was discussed in section V of this notice. To summarize briefly, EPA proposes that combustion emissions must be in steady state prior to sampling, such that essentially all (at least 90 percent) of the atypical elements entering the combustion chamber also exit in the vehicle exhaust. Steady state is to be determined by a mass balance using analytical protocols determined by the fuel/additive manufacturer. Mileage accumulation driving will be used to condition the vehicle until steady state is reached. If the atypical element has not reached steady after the minimum 25,000 mile requirement, mileage accumulation must continue. The producers involved will determine when to conduct additional testing to see when steady state has been reached. If the emission rate of the atypical compounds has not reached steady state within 80 percent of the useful life of the vehicle or engine, one final emission collection will be performed and the emissions analyzed for combustion products containing the atypical elements. The special Tier 1 emission characterization requirements for "atypical" fuels and additives will be considered complete at this point, under the assumption that elements not emitted during most of the useful life of the vehicle probably do not pose a significant health threat.

EPA asks for comments on whether the fate of all elements other than carbon, hydrogen, oxygen, nitrogen, and sulfur should be determined, or whether a select group of such elements should be subjected to these requirements. Also, comments are requested on the proposed requirements for determining the fate of atypical elements and whether initial steady state determinations should be allowed prior to 25,000 miles.

3. Quality Assurance

The accuracy of a testing program is a reflection of the repeatability and reproducibility of test results. Repeatability is a measure of the variation of results when tests are repeated on one set of equipment with all other variables constant, while reproducibility is a measure of the variation of results when an experiment is performed on different sets of equipment with all other variables constant.

This section proposes the adoption of some methods to ensure a high degree of accuracy for the emission characterization program.

a. *Repeatability.* While today's proposal suggests that repeatability should be determined by replicating each test or calibration, the emissions from a given vehicle are themselves subject to some variation. Thus, replicating vehicle-based tests to measure the repeatability of experimental equipment and procedures might yield misleading results. A more controlled approach would entail testing a set of known compounds periodically to determine the repeatability of test procedures. For this purpose, a prepared mixture of appropriate chemical compounds would be subjected to the protocols prior to testing the actual emission sample. These calibration tests would also be performed at intervals throughout the testing of fuel/additive emissions to assure continual satisfactory performance. Such tests are commonly used for calibrating chromatograph equipment. Comments are requested concerning the use of this or other proposed methods for assuring repeatable speciation results, including what compounds should be used for each procedure.

b. *Reproducibility.* Reproducibility is sometimes ascertained by implementing round robin testing of a given sample by a number of laboratories. The results of the round robin can determine the inherent procedural variation along with

[4] CRC Report No. 551 (1987) Chemical Methods for the Measurement of Unregulated Diesel Emissions. Coordinating Research Council, Inc. 219 Perimeter Center Parkway, Atlanta, GA 30346.

the quality of the labs performing the test. For example, if four labs obtained similar results for a known solution and one lab produced results that were significantly different, the reproducibility could be evaluated by the results of the four similar labs and the fifth lab could be excluded from further testing until the differences were resolved.

EPA asks for comments on possible arrangements for participating labs to perform speciation protocols in the context of a round robin program in order to determine test reproducibility and identify those labs capable of performing the required protocols with sufficent accuracy. To this end, labs wishing to take part in the testing program could voluntarily test a vehicle's emissions or analyze an unknown sample provided by EPA. If the results were accurate, EPA would have some assurance that the data generated by the lab would be acceptable.

c. *Audits.* EPA will reserve the right to audit testing facilities involved in the generation and characterization of emissions for purposes of fuel/additive registration so that the quality of results is assured. Such audits would be organized and administered by EPA at its own expense. The audit procedures could include a requirement that facilities submit a completed questionnaire in which equipment and procedural information would be described. EPA could make recommendatioins based on the submitted information and follow up with a visit to observe the performance of the protocols. The audit could also include EPA distribution of "blind" samples for analysis at participating laboratories. The audit would not have the purpose of certifying that the laboratory is "EPA approved". Rather, it would have the purpose of determining the weaknesses of labs and the acceptability of the lab's current performance. Comments would be appreciated on the implementation of laboratory auditing practices.

4. Other Emission Characterization Issues

a. *Emissions modeling.* The Reformulated Gasoline program (56 FR 31176, July 9, 1991) requires the extensive use of emissions modeling in place of actual speciation procedures to determine emission products. These models predict the combustion emissions from the fuel's composition. This approach was adopted because of its convenience, cost, and expected comparable accuracy for purposes of the program.

The "Simple Model" of the reformulated gasoline program uses a fuel's RVP, oxygen, benzene, and aromatic weight percents to predict the emission rate of non-methane volatile organic compounds, benzene, 1,3-butadiene, formaldehyde, acetaldehyde, and POM. In 1993, other fuel parameters will be included in the program's "Complex Model". However, these models fall far short of the speciation requirements proposed for this program. For example, benzene and 1,3-butadiene are only two of more than 100 hydrocarabons determined by the hydrocarbon speciation protocol proposed in section VI.A.2.b.

Given the differences in the goals and requirements of the two programs and a general lack of emission data to develop broader models, it may not be possible to meet the requirements of the present rulemaking using emissions modeling. This rulemaking involves the determination of various emissions from a wide variety of fuels and fuel additives. Some of the fuel additives contain compounds that are not common in fuels. Thus, emissions modeling does not appear to be adequate for this program and is not being proposed as an alternative means for determining emissions. Until models are capable of accurately predicting individual chemical species for entire classes of compounds, EPA regards emission generation and testing to be the only viable alternative. Nevertheless, EPA requests comment on the possible role of emissions modeling for fulfilling the emission characterization requirements in this proposed rulemaking, especially in regard to evaporative emissions, which seem somewhat more suited to modeling approaches. If use of the Simple or Complex Models is supported, EPA requests that a full justification be provided as to why the model results should be deemed to be equivalent to the results achieved under this program.

b. *Raw product testing.* Under the current fuel/additive registration program, fuel and fuel additive manufacturers are required to determine and report the composition of their products. However, few regulations have been promulgated governing the accuracy of this information and the procedures for raw product analysis. Particular short coming in the existing program are the underreporting of impurities which may be present in the fuels and fuel additives and the relatively broad reporting catgegories/criteria permitted for petroleum fuel constituents. With extensive emission speciation requirements now being proposed, it may be important to more clearly prescribe raw product analysis. A thorough raw product analysis along with the speciation results would provide a better picture of the combustion of fuels and fuel additives than the speciation results alone. Because one source of emissions is uncombusted fuel and additives, better information on the components of the raw products might identify potential emissions that are not measured in the standard emission characterization requirements. In addition, raw product testing would give more accurate information by which products could be grouped.

B. Tier 1: Data Research and Analysis

In addition to the emission characterization procedures described above, the requirements of Tier 1 include a comprehensive search and summary of available information sources concerning the emissions-based effects of fuels and fuel additives on the public health and welfare. Data modeling applications are also included. These requirements are discussed below.

1. Data Search and Summary

The major functions of the data search are twofold. The primary purposes is to furnish EPA with a useful compilation of existing information obtained from previous studies on the composition and potential toxicologic and environmental effects of fuel/additive emissions. This body of information is expected to provide a contextual overview as well as specific factual input for future regulatory decision-making by the Agency. For this purpose, the data search is to encompass available information on the chemical composition of the fuel/additive emissions and on all emissions-based health effects. That is, the required information is not restricted to the particular endpoints and experimental protocols included in Tier 2. The secondary function of the data search is to enable producers of fuels and additivies to document the extent to which the emissions characterization requirements of Tier 1 and the health effects endpoints included in Tier 2 have already been addressed by previous adequate testing. To mitigate the testing requirements of Tiers 1 and 2, reports of such previous testing will need to be sufficiently detailed to allow EPA to judge the adequacy of protocols, techniques, experimental design, statistical analyses, and data interpretation.

To the extent that such information is available, the data search should

address the chemical composition and potential adverse effects of whole combustion emissions, evaporative emissions, and relevant emission fractions (e.g., vapor phase and particulate phase). In addition, information should be sought for each of the individual emission products identified by the required emission speciation procedures, with the exception of the regulated emissions. In this regard, EPA requests comment on the necessity of requiring the data search to be done on identified emission products which are designated CAA title II or III air toxics.

Information considered applicable to a given fuel or additive includes data obtained from the testing of emissions from that specific product or from other similar products. Products would be considered similar to each other if they are members of the same fuel/additive group (as defined above in section IV) or if they qualify to be members of the same fuel/additive group. Thus, producers who choose to participate in group functions should pool information about all member products for purposes of their joint submission and should also make use of available data on other products which are not enrolled in the group but share the designated formulation characteristics of group members. Similarly, a producer who chooses not to participate in the grouping system should include any test results which may be available for products which could theoretically be assigned to the same group as the producer's own product.

Information on the health and environmental effects of fuels and additives is to be compiled from peer-reviewed scientific journals and other literature as well as internal industry studies, government-sponsored reports and assessments, proceedings of scientific meetings, and other documented sources. Reports of studies will be evaluated for adequacy using standard EPA guidance documents and basic toxicologic and ecologic principles. In general, EPA will place greater confidence in studies that have been subject to peer review.

Applicable studies may fall into a variety of categories. Evidence for potential toxicity or lack of toxicity in exposed humans may be available from epidemiologic studies, clinical studies, or case reports. More often, data will be available from experiments conducted with laboratory animals. In general, referenced experiments should be concerned with the health effects of inhalation exposure to fuel/additive emissions. However, data collected from studies using other routes of exposure may be included if there is sufficient justification to extrapolate the results to inhalation exposure. Short-term in vitro tests, comparative metabolism studies, structure-activity analyses, and the results of exposure modeling approaches are also considered relevant.

If available, data from field studies, monitoring exercises, accident evaluations, or environmental simulation experiments should be included to characterize the potential impact of fuel/additive emissions on vegetation, livestock, companion animals, wildlife, aquatic species, soil organisms, and natural and synthetic materials. Field and/or modeling studies on the environmental and atmospheric fate of fuel/additive emissions should also be included. In addition, the data search should cover studies concerning the contribution of the fuel/additive emissions to odor and visibility nuisances.

Proposed guidelines for conducting a comprehensive data search and policies for assessing the adequacy of various categories of referenced studies have been drafted in conjunction with the proposed petition process for adding or deleting pollutants to the lists of air toxics under CAA Section 112(b) (available in Central Docket Section A–130, EPA Docket No. A–90–48). EPA proposes to apply these general guidelines, instructions, and policies to the data search and summary requirements of the fuels/additives registration program. Consistent with these guidelines, a search of appropriate commercially available toxicologic and environmental data bases must be conducted to locate information from published sources. The search must go back for at least fifteen years prior to the date of submission, and must be current as of six months prior to the beginning of testing. Lists of appropriate commercially available data bases and suggested database search terms are provided in the draft air toxics petition guidelines referenced above. Given the long history of scientific experimentation with some fuel emissions, comment is requested on whether the data search period should extend back for a longer period of time, e.g., thirty years, rather than for only fifteen years.

The information to be submitted to EPA as a result of the data search includes the following items: (1) A brief text summary of the general findings and conclusions, (2) a printed copy of the outputs from the database searches, including reference list and associated abstracts, (3) complete documentation in scientific journal format of unpublished inhouse or other privately-conducted studies, and (4) tables summarizing the protocols and results of all cited studies, organized by health or environmental endpoint and type of emission (e.g., combustion, evaporation, and individual emission product). In addition, the person(s) or contractor(s) conducting the literature search and summary must be identified.

2. Modeling Approaches

EPA proposes to require the application of modeling or other analytic methods to provide estimates of ambient exposures to fuel/additive emissions, expected atmospheric reactivity of various emission products, and potential environmental partitioning of the emissions. The principles and parameters to be considered in implementing modeling approaches for vehicle emissions have been reviewed in the Health Effects Institute's publication, Air Pollution, the Automobile, and Public Health [5]. The choice of which models to use is left to the applicant, provided that the applicability, assumptions, limitations, and uncertainties of the models are clearly delineated. Several examples for consideration are described briefly below. However, new models are under development by scientists at EPA and elsewhere and the potential registrant would be required to use up-to-date techniques when conducting the analyses needed to meet Tier 1 requirements. Comments and suggestions from the public concerning the selection and application of analytic methods would be appreciated.

Ambient exposures. A microenvironmental model developed by Melvin N. Ingalls and Robert J. Garbe [6] is one possible method identified for deriving preliminary estimates of ambient exposures to emission products. This model estimates ambient concentrations of fuel/additive emissions, for each gram of emissions produced per vehicle mile (or vehicle minute), for "typical" and "severe" situations in six different microenvironments: Residential garage,

[5] Sexton, K. and Ryan, B.P., Assessment of Human Exposure to Air Pollution: Methods, Measurements, and Models and Russell, A.G., Mathematical Modeling of the Effect of Emission Sources on Atmospheric Pollutant Concentrations. In: Air Pollution, the Automobile, and Public Health. (1988) Health Effects Institute, National Academy Press, Washington, DC.

[6] Ingalls, M.N. and Garbe, R.J. (1982) Ambient Pollutant Concentrations for Mobile Sources in Microscale Situations. SAE Technical Paper Series 820767.

parking garage, roadway tunnel, street canyon, expressway, and expressway vicinity. Under this approach, the ambient concentration factors provided by the models could be used in conjunction with the measured emission rates for each fuel/additive emission product to estimate the exposure potential for each emission compound.

Specific population exposure characterizations are provided by the SIMSYS [7] [8] and SHAPES [9] models. Each of these methods uses both statistical and physical approaches to estimate emission exposures to individuals and to defined populations. SIMSYS can characterize high exposure situations and SHAPES can be used to model exposures to maximally-exposed or sensitive individuals. Once modelled, actual exposure data specific to the microenvironments could be used to validate the physical conditions predicted in these models.

EPA's Office of Mobile Sources is now completing the development of a new hybrid exposure model specific to mobile source emissions. The new model (HAPEM–MS) incorporates elements of both the Hazardous Air Pollutant Exposure Model (HAPEM),[10] which is more pertinent to stationary source air pollution, and another EPA model, the National Ambient Air Quality Standards Exposure Model (NEM).[11] [12] While based on carbon monoxide emissions, HAPEM–MS can be used to estimate the average annual exposure to any mobile source pollutant compound of interest, and expected to be highly applicable to the emissions exposure information needs of this program. A report describing HAPEM–MS and its uses is available in the public docket for this proposed rulemaking.[13]

Atmospheric transformation. EPA's OZIPM4 [14] and Urban Airshed [15] models are useful for calculating an ozone cost or benefit from specific emissions. In addition, a model developed for EPA and the California Air Resources Board by William Carter [16] provides estimates of the ozone-forming potential of volatile organic componds (VOCs) emitted by vehicles. The Carter model provides a set of scales representing the projected incremental effects of 140 different VOCs on the formation of photochemical ozone under a variety of urban airshed scenarios. Knowing the weight-percent concentration of individual fuel/additive emission products, the "maximum incremental reactivity" scales can be used to estimate the amount of ozone formed by these chemical species under conditions favorable to ozone production. However, uncertainties in the atmospheric chemical mechanisms related to many of the emitted VOCs may significantly affect the accuracy of these estimates. The usefulness of these models is also limited by the fact that they fail to provide information on potentially harmful atmospheric transformation products other than ozone. Thus, EPA is also considering an alternative approach. Rather than using mathematical models, a requirement could be established for analysis by a qualified chemist of the likely atmospheric fate of the emission species as a result of chemical reactions, deposition, and other processes. EPA would welcome comments from the public on the suitability of these or other approaches for estimating the atmospheric reactivity of fuel/additive emissions.

An argument can be made that requirements for the modeling of atmospheric reactivity would lead to redundant efforts by many manufacturers, since considerable overlap would be expected in the emission products of different fuels and additives (or groups). According to this argument, the duplicate efforts could be avoided if EPA itself were to run the models when needed, using the emission speciation data submitted by the fuel and additive manufacturers. Under this line of reasoning, once the data on primary emission products has been submitted, EPA would be in the best position to compare the emission profiles of different fuels and additives, and to use appropriate models to predict the implications for atmospheric reactivity.

While this argument appears to have some validity, it also contains some drawbacks. First, different manufacturers' submissions would be received by EPA at different times, interfering with EPA's ability to compare the emission profiles of various fuels and additives. Such comparisons would be difficult to perform in any case, and it is likely that EPA's attention would be drawn to fuels or additives which appear to generate unusually high concentrations of known precursors to harmful transformation products. As a result, fuels and additives which might provide a relative advantage in terms of atmospheric reactivity would tend to be overlooked. Such favorable results could be important in the overall evaluation of a fuel or additive for which certain adverse effects were also demonstrated. In addition, if EPA were to perform the modeling procedures, manufacturers would lost the initial opportunity to analyze and interpret the modeling results and conclusions for their products. Comments are requested on this possible approach.

Environmental partitioning. Examples of models which could be used to evaluate the environmental partitioning of emission products are the Spatial Multimedia Compartmental Model (SMCM), [17, 18] developed by the National Center for Intermedia Transport Research at UCLA, and Exposure and Ecotoxicity Estimation for Environmental Chemicals (E4CHEM), [19, 20] developed by Gesellschaft fuer Strahlen (GSF) of Munich, Germany. These publicly available models predict the concentration and mass fraction of pollutants in air, soil, water, sediment, and biota, thus indicating whether terrestrial or aquatic organisms are potentially at risk based on the

[7] Letz, R., et al. (1984) Estimated Distributions of Personal Exposure to Respirable Particles. Environ. Monit. Assess. 4:351–59.

[8] Ryan, P.B., et al. (1986) Estimating Personal Exposures to Nitrogen Dioxide. Environ. Int. 12:395–401.

[9] Ott, W.R. (1983–84) Exposure Estimates Based on Computer-Generated Activity Patterns. J. Toxicol. Clin. Toxicol. 21:97–128.

[10] Johnson, T., et al. The Assessment of Commuting Patterns in Applications of the Hazardous Air Pollutant Exposure Model. 84th Annual Meeting of the Air and Waste Management Association, Vancouver, BC, June 16–21, 1991.

[11] Johnson, T. and Paul, R.A. (1983) The NAAQS Exposure Model (NEM) Applied to Carbon Monoxide. PEDCo Environmental, Inc., Durham, NC. EPA–450/5–83–004.

[12] Ingalls, M.N. (1985) Improved Mobile Source Exposure Estimation. Southwest Research Institute, San Antonio, TX. EPA–460/3–85–002.

[13] Johnson, T., Paul, R.A., and Capel, J.E. (1992) Application of the Hazardous Air Pollutant Exposure Model (HAPEM) to Mobile Source Pollutants. International Technology Corporation, Durham, NC. EPA Contract No. 68–DO–0062.

[14] Hogo, H. and Gery, M.W. (1990) User's Manual for OZIPM4 (Ozone Isopleth Plotting with Optional Mechanisms), Volume I. Systems Applic, Inc, San Raphael, CA. EPA–450/4–89–009a.

[15] Morris, R.E., et al. (1990) User's Guide for the Urban Airshed Model, Volume I. Systems Applic Inc, San Raphael, CA. EPA–450/4/90–007A.

[16] Carter, W.P.L. (1990) Development of Ozone Reactivity Scales for Volatile Organic Compounds. Statewide Air Pollution Research Center, Riverside, CA. U.S. EPA Contract CR–814396–01–0.

[17] Cohen, Y. et al. (1990) Dynamic Partitioning of Organic Chemicals in Regional Environments: A Multimedia Screening-Level Approach, Environ. Sci. Technol. 24:1549–1558.

[18] Tsai, W., et al. (1991) Hydrogen Peroxide Levels in Los Angeles: A Screening-Level Evaluation. Atmos. Env. 25B:67–78.

[19] Trenkle, R. (1988) Fate Simulation of Organic Substances in the Atmospheric Mixing Layer. In: Environmental Meteorology, K. Grefen and J. Lobel (eds), Kluwer Academic Publishers.

[20] Matthies, M. et Al. (1989) Exposure and Ecotoxicity Estimation for Environmental Chemicals (E4CHEM): Application of Fate Models for Surface Water and Soil. Ecol. Model. 47:115–130.

environmental partitioning of the pollutants to these specific environmental media.

C. Tier 2 Requirements

The second tier of health effects evaluation consists of short-term screening tests which address the health endpoints previously described. These tests will be required for all fuels and additives to the extent that the results of the data search activities in Tier 1 do not include comparable existing information from adequately performed and properly documented previous studies. Criteria for assessing the adequacy of such studies were addressed in section III.E.3 of this proposal. EPA requests comment on whether there are other circumstances or product characteristics which would indicate that certain fuel families (e.g., methane or propane) should be exempted from particular Tier 2 testing requirements.

The proposed health effects testing guidelines are included in the regulatory text for this proposal, available in the public docket or by request to EPA (see the section of this Notice entitled, "For Further Information"). Most of these testing guidelines are modified versions of guidelines previously published under TSCA (40 CFR part 798). Methods for performing animal inhalation exposures to fuel/additive emissions are also included in the proposed regulatory text. Comments and suggestons are solicited on the adequacy of these proposed guidelines and methodologies for promoting valid study design and adquate technical performance. EPA believes that these guidelines (perhaps amended for the Final Rule as a result of submitted commentary), together with published laboratory practice standards (referenced below), are sufficient to ensure that Tier 2 testing done in conformance with these guidelines will be acceptable upon subsequent evaluation by EPA. However, comments are requested on whether an optional review mechanism should nevertheless be established, enabling manufacturers to submit detailed protocols to EPA for approval before beginning Tier 2 testing. Under such a review process, protocols reviewed by EPA would earn a presumption of technical adequancy, but in view of the large number of individual protocols which might be submitted for review, significant testing delays could occur. Thus, respondents who believe that a review mechanism is necessary or useful are asked for suggestions on how to make the process operate efficiently and effectively, given the statutory time constraints for program compliance.

Similar requirements among the various test guidelines in regard to animal subjects, exposure scenarios, and general technical principles provide opportunities for concurrent test performance at considerable cost savings. These shared study parameters include the following:

Laboratory Practices

To ensure the quality and integrity of test results, the performance of all studies will be required to conform with the Good Laboratory Practice Standards (GLPS) published in 40 CFR part 792, or with comparable standards which may be developed specifically for this program. These GLPS include facility, equipment, organization, quality assurance, and personnel requirements, as well as specifications for proper care of laboratory animals, handling of reagents and test substances, and conduct of studies. In addition, the provisions of subpart J of part 792 are to be followed for record keeping and reporting of results.

Animal Models

With the exception of the Ames Salmonella assay, the proposed test requirements entail the exposure of live laboratory animals to fuel/additive emissions. Mammalian species are required, with rodent species recommended. The developmental toxicity study calls for the exposure and assessment of two species, while the other studies require only one species to be tested. Animal facilities must be operated in compliance with the Animal Welfare Act as amended and in compliance with all pertinent USDA regulations.

Exposure Routes

Most of the proposed tests are based on the inhalation exposure of laboratory animals to diluted whole exhaust and evaporative emissions. Such studies require an exposure system designed to ensure the controlled generation, dilution, and delivery of emissions to the laboratory animals. To this end, a section of the proposed regulations provides a discussion of methodologies for conveying either combustion or evaporative emissions to the test animals, exposure parameters which need to be monitored and documented during the course of the inhalation exposure period, and animal care issues. Additional information on the hardware requirements, maintenance, and use of emission generation and inhalation systems can be found in "General Health Testing Guideline for Inhalation Exposure to Fuels and Fuel Additives", (Cheng and Barr, 1991), available in public docket A–90–07.

In the case of the in vitro Ames assay, bacterial cell cultures rather than live animals are exposed to the test emissions. This assay is to be performed using prepared fractions of combustion emissions, including an extract of filtered particulate matter [21] and an extract of a sorbent resin which traps semi-volatile gases [22]. The Ames assay will not be required for evaporative emissions.

Exposure Duration, Dosages, and Controls

The results of recent studies on inhaled vehicle exhaust mixtures, as compared with similar tests using concentrated solutions of single chemicals, indicate that exposure durations of five weeks or less may not be sufficient to induce observable toxicologic changes. Traditionally, the next step up in exposure duration is to a 90-day subchronic test. Because of cost considerations, however, the proposed test guidelines generally call for a minimum six week (42 day) exposure period for at least six consecutive hours per day, seven days per week. EPA requests comment on the adequacy of the proposed exposure and on the potential importance of extending these tests to 90 days for comparability to historical data.

Each study requires exposures to be conducted at a minimum of three dilutions, corresponding to low, midrange, and overtly toxic concentrations. A control group exposed to filtered conditioned air is also required. The objective is to choose exposure levels that will provide a lowest-observed-adverse-effect level (LOAEL) and a no-observed-adverse-effect level (NOAEL). In recognition of the possibility that even high levels may be nontoxic, provisions are made for "limit tests", where appropriate.

Tests conducted specifically for determining the emissions effects of additives, which involve mixing the additive with an appropriate fuel prior to emission generation, require additional control studies using the emissions of the base fuel alone. A possible means of meeting the

[21] Huisingh, J. L., et al. Mutagenic and Carcinogenic Potency of Extracts of Diesel and Related Environmental Emissions: Study Design, Sample Generation, Collection, and Preparation. In: Health Effects of Diesel Engine Emissions, Vol. II. W. E. Pepelko, et al. (Eds.); US EPA, Cincinnati, 1980, EPA–600/9–80–057b, pp. 786–800.

[22] Stump, F., Snow, R., et al. (1982) Trapping Gaseous Hydrocarbons for Mutagenic Testing. SAE Technical Paper Series No. 820776.

requirement for base fuel control testing without duplicative effort was discussed previously in section V.

Brief descriptions of the proposed test guidelines for each health endpoint are provided in the following sections. A possible alternative testing approach is also described.

1. Carcinogenicity and Mutagenicity Screens

A battery of three screening studies is proposed, as described below. In these studies, mutagenic and/or carcinogenic activity is indicated by a statistically significant concentration-related increase in positive responses after exposure to fuel/additive emissions as compared to controls (i.e., animals exposed to filtered air and, in the case of additive testing, animals exposed to emissions of the base fuel). The detection of a reproducible and statistically significant positive response to at least one concentration of emissions may also be interpreted as a positive result.

Ames reverse mutation assay. The Ames assay is an in vitro test for mutagenicity and, by implication, for carcinogenicity. The assay makes use of five mutant strains of the bacterium Salmonella typhimurium which cannot grow in a medium deficient in histidine due to an inherited inability to produce this amino acid. Exposure to mutagenic (and possibly carcinogenic) subtances can elicit reverse mutations, such that the bacteria regain their ability to grow in a histidine-deficient medium. In this test, bacteria will be exposed to the soluble organic (semi-volatile) and particulate extracts of fuel/additive combustion emissions. (Ames tests will not be required for evaporative emissions or for the gaseous fraction of combusion emissions.) After exposure, the cells will be plated on histidine/deficient media, both with and without metabolic activation, and incubated for a designated period of time. The number of colonies (revertants) growing on the plates will then be compared to the number of spontaneous revertants in control cultures.

In vivo micronucleus assay. Micronuclei are sub-cellular structures containing chromosomes and chromosome fragments not incorporated into the main nucleus during cell division. While micronuclei do form under natural conditions, exposure to potentially carcinogenic agents can cause an increase in micronucleated cells. In this assay, live rodents will be exposed by inhalation to the fuel/additive emissions. Subsequently, erythrocytes obtained from the peripheral blood (or, in rats, from the bone marrow) will be sampled, stained, and viewed under a light microscope. The number of normochromatic erythrocytes containing micronuclei will then be counted and compared with normochromatic erythrocytes from untreated animals. The use of erythrocytes in this procedure facilitates the visualization of micronuclei, since their primary nucleus is normally extruded during cell development.

In viro sister chromatid exchange (SCE). SCEs are believed to be caused by chromosome strand breakage resulting in exchanges of genetic material between the halves of a chromosome "pair" (i.e., the chromatids). While some SCEs occur normally, an increase in the frequency of such exchanges may be indicative of mutagenic/carcinogenic activity. In this assay, animals which have undergone inhalation exposure to vehicle emissions will be sacrificed and peripheral blood lymphocytes as well as cells from lung tissue will be isolated and cultured. The cells will be treated with a DNA base analog (bromodeoxyuridine, BrdU) and with a spindle inhibitor such as colchicine. After appropriate staining for labeled DNA, sister chromatid exchanges will be scored from cells arrested in the second mitotic division and the results compared with appropriate controls.

2. Developmental Toxicity (Teratogenicity) Study

This study is designed to provide information on potential dangers to the unborn which may arise from inhalation exposure of the female to fuel/additive emissions during pregnancy. Pregnant animals will be exposed to emissions during the major organ development period in the fetus (e.g., days 6–15 for rats and mice). The dams will be sacrificed on the day prior to normal parturition and the uterus examined for embryonic or fetal deaths. Viable fetuses will be examined for skeletal and soft tissue anomalies. These results will be evaluated relative to the number of spontaneous embryonic or fetal deaths and abnormalities in appropriate controls. The initially proposed test guidelines for developmental toxicity calls for two different species to be examined. However, EPA asks for comment on whether one species would be sufficient for the screening purposes of Tier 2.

3. Reproduction and Fertility Screen

The purpose of this test is to determine the potential reproductive toxicity to adult male and female animals caused by inhalation of fuel/additive emissions. Both males and females will be exposed to the emissions throughout an initial 42-day exposure period. In females, vaginal cell smears will be examined throughout this time, to track effects on the estrous cycle. At the end of the initial exposure period, a sufficient number of females will be mated to obtain at least ten pregnant females. Histopathological examination of the uterus and ovaries will be performed on the non-pregnant females, while the adult males will be evaluated by gross and histopathological examination of the reproductive organs and by assessing the number, morphology, and motility of sperm. Pregnant females will continue to be exposed to the test atmosphere throughout the pregnancy, and will be examined, along with their offspring, at the time of birth and at four days post-partum.

As compared with appropriate control animals, positive results would include changes in the number and type of cells seen in vaginal smears, decreases in sperm number or motility or abnormalities of sperm structure, and pathologic changes found during gross or microscopic examination of male or female reproductive organs. A decrease in the number or viability of offspring would also be evidence of toxicity.

4. Pulmonary Toxicity Screen

This study involves a six-week inhalation exposure of laboratory rodents to fuel/additive emissions, with subsequent examination of lung tissues and cells. A satellite group of rodents (with control animals) will be exposed to the highest concentration of emissions in the study for only one week. Lung lavage will be performed on the satellite group to obtain alveolar macrophages for assay of phagocytic activity and fluids for biochemical analysis. Positive results at the end of the exposure period would be indicated by elevated enzyme or total protein levels, elevated numbers of cell types normally found in the lungs, a low index or lack of phagocytic activity, and abnormal gross or histopathological findings relative to appropriate control animals. Persistence or delayed occurrence of toxic effects beyond the exposure period would also indicate positive results.

5. Neurotoxicity Screen

The proposed screen for neurologic effects is a functional observational neurotoxicity battery (FONB) which is to be performed on live animals periodically throughout a six-week period of inhalation exposure to fuel/additive emissions. Using standardized

procedures and both positive and negative controls to minimize observer variablility, the functional battery will include the assessment of autonomic activity, alertness, gross movement, behavior, gait, grip strength, and reactivity to general stimuli. As compared with the controls, positive results would include any of the following responses and changes: Unusual body position, activity level, coordination, gait or behavior, tremors or convulsions, increased lacrimation or salvation, piloerection, pupillary changes, unusual respiration, diarrhea, increased of decreased urination, unusual vocalization, and decreased grip strength.

To completely assess the neurotoxic potential of complex fuel/additive emissions, additional functional and neurohistochemical tests would be necessary. Used alone, the FONB may overlook adverse effects at the celluar level. Thus, EPA requests comment on whether an in vitro assay for determining the level of glial fibrillary acidic protein (GFAP) [23,24] should be required in addition to the FONB to broadly assess sensitive neurohistopathologic effects in test animals. Another alternative is to delete the FONB and to address neurotoxicity by requiring only the GFAP assay. The GFAP assay is a sensitive indicator of adverse neurotoxicologic effects. Because it is an *in vitro* test which can make use of brain tissue harvested from exposed animals used in other studies, it is also a relatively inexpensive option. EPA requests comment on these alternative approaches for Tier 2 testing of neurotoxic effects.

6. Optional Histopathology

If the Tier 1 literature search or emissions characterization suggest the potential for toxicity to other organ systems, then histopathology of the indicated organs should be performed, using the animals exposed in the pulmonary toxicity screen. For example, if adverse effects to the liver appear likely, as suggested from the literature or the presence of high levels of PAHs in the emissions, then it would be advisable to perform histopathology of the liver. On the other hand, if scientifically sound studies reported in the literature indicate no or very minimal potential for hepatic effects, then liver examination would not be necessary. Other organ systems likely to be of concern include the kidneys and the endocrine glands. These additional examinations are suggested because findings of potential adverse health effects in Tier 1 might require follow-up at the Tier 3 level, and if performed as adjuncts to required Tier 2 testing, these optional histopathology examinations might provide substantial incremental information at a relatively low incremental cost. At a minimum, organs of potential concern should be removed, weighed, and saved in storage for potential histopathological examination at a future time. However, the length of time which organs can be stored and still be of use is limited. EPA requests comment on whether histopathological examination of the liver, kidneys, and endocrine glands as an adjunct to the pulmonary toxicity screening test should be required rather than optional.

7. Alternative Testing Approach

An alternative approach under consideration by EPA in place of some of the proposed Tier 2 tests described above is a modified version of a protocol developed for use by the Organization for Economic Cooperation and Development (OECD). The protocol, which was developed for use in the OECD's Screening Information Data Set (SIDS) testing program on high volume chemicals, is a screening test which was initially developed in the U.S. by experts from the government, industry, academia, and environmental groups. It is presently in use for certain toxicology applications by 14 countries which are members of the OECD as well as by EPA's Office of Toxic Substances. The standard protocol is designed as a single-study screen for repeat dose, reproductive, and developmental effects. Currently, efforts are underway at EPA to add neurotoxicity measures to the protocol, as well. Documentation about the SIDS protocol is available in the public docket for this rulemaking.

While the SIDS protocol might need some further modification to accommodate exposures by inhalation to fuel/additive emissions, it could potentially be used in place of the pulmonary, reproductive, developmental, and neurotoxicity screening tests described previously. In performing the SIDS test, both male and female rats would be exposed for a 45-day period. Males would then be examined for repeat dose (including pulmonary) effects, reproductive effects (sperm number, sperm morphology, histopathology of the testis, etc.), and neurotoxicity. Females would be evaluated for reproductive performance, developmental effects and, possibly, pulmonary effects.

While some of the proposed individual tests could be performed simultaneously in order to reduce emission generation and exposure costs, the SIDS study evaluates the four specified health effects endpoints in a single protocol, and might offer additional cost savings. On the other hand, the SIDS study is more complex and the results would include somewhat less information for each endpoint in comparison with the proposed individual tests. Comments are requested concerning the use of the modified SIDS study as a single-protocol substitute for the four specified individual screening tests.

D. Tier 3 Requirements

Fuels and additives would be subject to additional testing under the proposed Tier 3 provisions of the registration program as determined on a case-by-case basis by EPA. The endpoints to be addressed and the nature of the studies to be performed would depend on the case at hand. Since the overall objective of the program is to adequately characterize the risk of exposure to fuel and fuel additive emissions, the applicable Tier 3 requirements could include chemical analyses, health studies, and/or exposure studies. As discussed in Section III, these tests would most often be required to further explicate the results of the screening batteries performed under Tier 2, but might also address other areas of concern highlighted by the Tier 1 literature search or emission characterization procedures. The need for Tier 3 testing would depend on whether sufficient toxicity and exposure information were available to determine whether use of a fuel or fuel additive presents an unacceptable health risk. The criteria for this determination are discussed below.

When a determination has been made that Tier 3 testing will be required, EPA will inform the responsible producer(s) by certified mail of the purpose and nature of the testing to be performed. Subsequently, relevant study guidelines and a timetable for completion of all requirements will be specified. The producer(s) will be expected to submit detailed protocols for review and approval by EPA prior to beginning the tests. Tier 3 testing performed in full conformity with a protocol pre-approved by EPA for the given product(s) and test objective will be deemed satisfactory compliance with the Tier 3 testing requirement.

[23] In: Pesticide Assessment Guidelines, Subdivision F, Neurotoxicity Test Guidelines (1991). EPA–540/09–91–123.

[24] O'Callaghan, J.P. (1991) Quantification of Glial Fibrillary Acidic Protein: Comparison of Slot-Immunobinding Assays with a Novel Sandwich ELISA. Neurotoxicology and Teratology, 13:275–281.

1. Need for Discretionary Tier 3 Determinations

Given the variety of evaluation methodologies and subjects included in Tiers 1 and 2 and the wide range of possible interrelated outcomes which could be obtained, EPA believes that it is neither practical nor necessarily desirable to specify precise and exclusive criteria which would automatically cause fuels and additives to be subject to Tier 3 requirements. In nearly all cases, decisions on the need for Tier 3 will ultimately depend on expert scientific judgment as to the quality of the evaluation of potential health risks which would be possible from the available data and the need for more definitive information in developing future regulatory strategies.

Case-by-case judgments would be expected to play a significant role in determining if Tier 3 is required even at the extremes of possible Tier 1 and 2 outcomes. For example, a high potential exposure combined with positive Tier 2 test results might not necessarily call for Tier 3 follow-up if literature search or other supporting information were available to adequately characterize the potential public health risks involved. Conversely, relatively low estimated exposures and equivocal test results might not remove the need for further evaluation if the test results were inconsistent with other available information or with known emission product toxicities or if exposures were expected to rise significantly in the future. In general, because of their potentially widespread distribution and use, most fuels and high-volume bulk additives would have a sufficiently high exposure potential to indicate a need for Tier 3 testing, provided that Tier 1 and 2 data suggested the likelihood of adverse health effects.

The discretionary nature of the decision process means that the elevation of a product (or group of products) to Tier 3 need not invariably lead to studies of chronic duration. Depending on the endpoints and protocols involved, additional short-term analyses, subchronic toxicity tests, and/or pharmacokinetic studies might be sufficient to clarify risks or allay concerns.

Because Tier 3 requirements are proposed to be applied on a discretionary basis, and because the scope of such requirements could be tailored to address individual circumstances, the Tier 3 mechanism would help to ensure that financial resources and laboratory capacity would be invested in areas of real concern. A possible alternative approach would involve the establishment of automatic "triggers", i.e., specific outcomes of Tiers 1 and 2 which would make Tier 3 testing mandatory. Associated Tier 3 testing requirements would also be specified in advance for each trigger. To ensure that significant concerns would not be overlooked under this approach, however, relatively conservative conditions would need to be designated to serve as the Tier 3 triggers, and relatively stringent testing scenarios specified as automatic follow-up regimens. As a result, Tier 3 might be triggered more frequently and might include more rigorous testing requirements that would occur under the proposed discretionary approach. On the other hand, a system of automatic Tier 3 triggers and test requirements would better enable manufacturers to predict and plan for their maximum registration responsibilities and would simplify EPA's data evaluation tasks. EPA requests comment on the relative merits of the discretionary vs. automatic approaches for determining Tier 3 applicability. Respondents who prefer the automatic approach are also asked for suggestions as to the specific "triggers" and follow-up tests which should be established.

While EPA proposes to retain discretion in the decision to require Tier 3 testing, it is possible to predict some sets of circumstances which would indicate that Tier 3 will *not* be required. These factors are discussed in the sections which follow. EPA requests comments on these circumstances, and asks for suggestions on other combinations of criteria ("bright lines") which could be established to determine that consideration for elevation to Tier 3 is unnecessary.

2. Criteria for Escalation to Tier 3

This section presents some of the guidelines and considerations which EPA would use in determining the necessity for additional testing under a discretionary Tier 3 testing approach. Consistent with the proposed discretionary decision-making process for Tier 3, this discussion is not intended to provide an exhaustive or definitive listing of relevant criteria. Rather, the major purpose of this discussion is to help furnish a basis for meaningful public comments and suggestions on the proposed Tier 3 provisions.

The decision to require manufacturers to submit additional testing on the health effects of fuel and fuel additive emissions would take into account the cumulative information provided by Tiers 1 and 2, including previous scientific data, emissions characterization data, modeling outcomes, and biological test results. Thus, decisions to require Tier 3 would be made only after the requirements of Tiers 1 and 2 have been adequately filled. Adherence to this principle will prevent unnecessarily costly or poorly targeted decisions based on piecemeal, out-of-context information, and will promote more precise identification and evaluation of data gaps and more cost-efficient coordination of potential test requirements.

Ultimately, EPA must be able to decide whether the use of a fuel or additive is likely to create unacceptable health risks. If this decision is made possible by the information from Tiers 1 and 2, then Tier 3 would not be needed. However, if such a risk decision cannot be made on the basis of the Tier 1 and 2 data, then Tier 3 testing would be required. Therefore, to make a determination on the need for Tier 3 testing, EPA scientists would evaluate the extent to which the results of Tiers 1 and 2 were adequate for such decisions, guided by the basic principles of risk assessment. A risk assessment involves the merging of a health effects assessment (including hazard identification and dose-response relationships) and an exposure assessment. Such an assessment can range from a qualitative to a highly quantitative analysis, depending upon the extent of the available data.

In most cases, a highly quantitative assessment would probably not be possible at the end of Tier 2. However, Tiers 1 and 2 might indicate that little hazard is present and that such exposures are quite low and limited geographically. In such a case, there would be little reason to pursue further testing at the Tier 3 level to improve dose-response information. In another example, Tiers 1 and 2 might suggest that a hazard is likely and that exposures appear significant, but the data may still be inadequate for a quantitatively advanced risk assessment. In this case, Tier 3 testing, targeted to provide the missing information, would be indicated.

In this way, the principles and critical data elements of the risk assessment process would provide a useful guide for identifying significant information gaps and determining the specific objectives of potential Tier 3 testing. However, EPA does not intend to conduct a formal risk assessment as part of its decision on whether to promote a fuel or fuel additive (or group) to Tier 3. Rather, EPA would evaluate the quality and certainty of available toxicity and dose-response data and consider qualitatively

whether estimated exposure weighs in favor of or against further testing. On this basis, EPA would determine whether additional information is necessary to adequately assess the risk of fuel or additive. A formal risk assessment would be more likely to be developed later if there was a need for action to control or prohibit a product under the regulatory authority of section 211(c).

The following section discuss the key factors which EPA would consider in identifying the need for and content of Tier 3 testing.

a. Statistical issues. As previously mentioned, scientific judgment will be exercised in determining whether Tier 3 tests are necessary and, if so, which ones. An important factor in such judgments will be the interpretation of and significance ascribed to "negative" results obtained in Tiers 1 and 2. Evaluating negative data (i.e., no-effect data) can be more difficult than evaluating positive data, because questions often arise as to the reason for the negative result: Did aspects of the experimental design (e.g., very small numbers of animals) lead to the negative outcome or was the test substance inherently of very low or no toxicity?

This specific question is addressed statistically by considering the probability of Type I and Type II errors. A Type I error occurs when a false positive conclusion is made, while a Type II error is a false negative conclusion. The acceptability of a specific Type II error is related to the acceptability of false negatives in the particular study being performed. For example, from a toxicological perspective, screening assays often have a relatively high probability of producing false negative outcomes, since some major aspects of organ or tissue toxicity are not being examined. Thus, an acceptable Type II error for screening assays would typically be low. However, the level of Type II error considered acceptable should be tempered by the goal of the study. A higher false negative conclusion (e.g., Type II error of 0.2) would generally be acceptable if it referred to an effect of minimal severity at a high-exposure test level relative to ambient concentration and if few people were likely to be exposed. The converse would also hold true.

A number of factors increase the complexity of these statistical issues. For example, the design of the study will influence the Type I and II levels obtained and the standard statistical methods chosen. Therefore, the scientific quality of the statistical analyses and their relationship to the experimental design are quite important. For example, although minimum sample sizes are specified in the proposed regulations, these are only general guidelines. Variability between laboratories and the specifics of the study methods may allow a decrease or require an increase in sample size. These possibilities should be evaluated properly before the start of the study.

In summary, scientifically sound statistical analyses are a crucial part of any good study and will provide key information for EPA to use in forming judgments on whether or not Tier 3 testing is needed. While it is not feasible to list all possible scenarios and results for each Tier 2 endpoint, the foregoing discussion elucidates how some of the statistical factors will be incorporated in EPA's decisions.

b. Exposure assessment. A number of the proposed Tier 1 and 2 requirements will provide EPA with information on population exposures to fuel and additive emissions. This information includes (1) historical and/or projected production volumes, (2) types and emission rates of speciated emission components, (3) estimated urban, rural, and/or microenvironment exposures obtained through exposure modeling approaches, (4) evidence for bioconcentration from environmental modeling results, and (5) possible literature search findings on ambient, occupational, or epidemiological exposures. As mentioned above, this information will be considered qualitatively by EPA in determining whether Tier 3 testing is needed.

Significant public health concerns might sometimes be revealed by the exposure information itself. This might be the case, for example, if there were an anticipated release in excess of, say, 1,000 kg per year of individual emission compounds (in addition to "criteria" pollutants) with known toxicities, or if the anticipated exposure scenarios approached or exceeded current estimates of apparently safe levels of known toxicants. In the case of fuels and their associated high-volume bulk additives, EPA will generally assume that human and environmental exposures will be of sufficient level and extent that significant observed adverse effects would indicate a need for follow-up in Tier 3. This exposure assumption reflects the high production and consumption of these products, either at the present time or as anticipated in the future. Thus, decisions to promote these products to Tier 3 would be based on the degree to which additional testing is needed to clarify the results and potential health effect implications of Tier 1 and Tier 2 data. It cannot be assumed, on the other hand, that fuel additives used in relatively low concentrations or produced in relatively low volumes would automatically be excused from Tier 3. For these products, test results indicative of severe health effects and/or high exposure levels in circumscribed areas might be cause for escalation to Tier 3.

c. Health assessment. General criteria for evaluating the potential public health effects associated with fuel and additive emissions would include (1) the number of positive and negative outcomes related to each endpoint, (2) the identification of concentration-effect relationships, (3) the statistical sensitivity and significance of such studies, (4) the severity of the observed effects (e.g., whether the effects would be likely to lead to incapacitating or irreversible conditions), (5) the number of species involved in the reported tests, and (6) the consistency and clarity of apparent mechanisms, target organs, and outcomes. Additional parameters which would influence the decision on whether to require Tier 3 would include (1) findings of environmental persistence of the emissions and/or the ability of the emissions to accumulate in living organisms, (2) the nature and amount of known toxic agents in the emissions stream, and (3) the observation of lesions which specifically implicate inhalation as an important exposure route for inducing adverse health effects.

These criteria would be evaluated in conjunction with the results of the exposure assessment to determine whether or not higher level testing was needed. In this decision, both the biological and statistical significance of the results of Tiers 1 and 2 would be taken into account. Generally, escalation to Tier 3 would be considered when remaining uncertainties about the significance of observed outcomes and/or exposures interfered with EPA's ability to make reasonable estimates of the attendant public health risks. On the other hand, if no statistically significant effects were obtained at any exposure level in a scientifically sound Tier 2 study (or existing test submitted in lieu of Tier 2 testing and not contradicted by other published reports of equal or greater reliability), and if other major sources of concern did not arise (e.g., toxic effects of structurally related compounds), then Tier 3 testing would not be required for the endpoint in question. This assumes that relevant, high-quality statistical analysis had been done to permit the negative test results to be properly evaluated and interpreted. The statistical analyses

recommended for Tier 2 in an earlier discussion, including determination of Type I and II error, should enable reasonable conclusions to be drawn as to the significance of negative findings. Factors to be taken into account include the toxicological nature of the findings and the exposure levels used in the test. For example, if the statistical analyses were applied to a "severe" endpoint (e.g., major fetal abnormalities, major lung pathology, etc.) and the exposure in question was moderate, then 0.1 would be an appropriate Type II error level. In contrast, if a high concentration limit test caused a relatively minor effect (e.g., a small change in lung lavage protein), a higher Type II error would be allowed (e.g., 0.2), effectively increasing the chance of false negative conclusions.

Evaluation of Tier 2 results. The specific outcomes which would be considered positive and negative results for each proposed Tier 2 test are mentioned briefly in the previous descriptions of Tier 2 requirements and are defined and interpreted more precisely in the proposed regulatory text. For example, three primary studies are included in Tier 2 which relate to carcinogenicity and mutagenicity: the Ames, SCE, and micronucleus assays. As compared with appropriate controls, a statistically significant dose-related positive response in any one of these assays could be cause for concern, as would positive outcomes for at least one concentration in two or more of these tests. Such outcomes would be indicative of mutagenic risk; however, depending on the internal and historical consistency of these results and their relationship to projected exposures, further testing might be required to determine the significance of this mutagenic activity in human populations exposed by inhalation. These outcomes would also indicate that the emissions could initiate some of the mechanisms involved in carcinogenesis. However, the production of malignancy is a multi-step process, and these results would generally not in themselves be sufficient to determine whether the emissions were in fact carcinogenic. Thus, additional testing might be required under Tier 3 to better evaluate the associated cancer risks. In contrast, if no statistically significant results were obtained in these three assays and no conflicting results found in the literature or in other Tier 2 tests, then Tier 3 follow-up for carcinogenicity/mutagencity would not be required.

To take another example, determination of the need to further investigate teratogenic risks would take into account the results of both the inhalation developmental toxicity study and the reproduction and fertility assessment of Tier 2. If negative results were obtained in both of these tests (according to statistically sound principles), and if these results were not refuted by the existing literature, then additional testing would not be required at the Tier 3 level for developmental or reproductive effects. Positive results would include a decrease in neonatal viability relative to that in control studies, a significant change in the proportion of viable male vs. female fetuses or offspring, the presence of soft tissue or skeletal abnormalities, and an increased rate of embryonic or fetal resorption. Other positive outcomes of the reproduction and fertility assessment, such as abnormal changes in sperm structure or function, vaginal cytology, or reproductive organ histopathology, would be indicative of hazards to the adult reproductive systems. The need for additional evaluation under Tier 3 would depend on the number of species from which positive results were obtained, the specificity, severity, and consistency of results, the presence or absence of a concentration-effect relationship, and the significance of these outcomes in view of projected exposure scenarios. The greater the remaining uncertainty regarding the risk of teratogenic or reproductive effects after analysis of such factors, the higher would be the likelihood that Tier 3 would be required.

Similarly, consistent negative results (according to statistically sound principles) obtained in other Tier 2 tests, in the absence of significant related concerns raised in the literature, would make Tier 3 unnecessary. On the other hand, if adverse effects are found at Tier 2 and/or reported in the literature, EPA would determine if Tier 3 follow-up is required by attempting to evaluate the nature, severity, and significance of the findings in light of the likely exposures. If EPA determines that Tier 3 testing is required to resolve the remaining uncertainties, the Tier 3 requirements would reflect both positive and negative results. For example, if the results of Tier 2 were positive for pulmonary effects but negative for neurotoxicity (according to criteria discussed earlier), and if these results were consistent with the literature, only pulmonary toxicity would be a likely candidate for Tier 3 follow-up testing.

Acute health assessment. Under the assumption that emissions exposures will generally be low and thus more likely to cause longer-term effects, this proposed rulemaking does not focus on acute effects. However, the purpose of CAA section 211 is to protect the public health, whatever the exposure duration, and potential acute effects could also be a consideration in the Tier 3 decision.

EPA is currently developing a standardized method of assessing acute noncancer health effects, and this method might be useful for evaluations under this proposal program. The new method will estimate levels of exposure which are expected to pose no or minimal health risk to susceptible subpopulations as well as levels posing incrementally higher risks. A draft of this method is expected in early fiscal year 1993. After a period for comment by EPA's Scientific Advisory Board (SAB) and the public, a final draft is expected in fiscal year 1994. Thus, the new methodology may be available for use in a time frame consistent with the needs of this program. If acute risk must be assessed prior to the availability of the approved methodology, then expert judgment approaches could be applied. EPA seeks comment on these possible methods for taking acute health effects into account in the determination of Tier 3 requirements.

Inhalation reference concentrations. Another standardized methodology under development by EPA might also be applicable to decisions on whether to require Tier 3. This process, the inhalation reference concentration (RfC) methodology, is currently in draft form. After incorporation of revisions based on SAB and public comments, the report is expected to be finalized in fiscal year 1992. From time to time, EPA will be revising this methodology to reflect advances in the state of the art.

While the present RfC methodology recognizes subchronic data, it focuses on chronic data, since the RfC is intended to address health risk due to lifetime exposures. Specifically, a chronic RfC is an estimate of a daily inhalation exposure to humans (including sensitive subpopulations) thought to be without appreciable noncancer risk over a 70-year lifetime. The minimum data base required to develop a chronic RfC includes at least a 90-day inhalation exposure that thoroughly addresses the potential for respiratory tract toxicity and establishes a lowest-observed-adverse-effect level (LOAEL) and a no-observed-adverse-effect level (NOAEL) for a "critical effect." This is a sensitive endpoint that plausibly protects against other less sensitive effects. The NOAEL and LOAEL are adjusted with dosimetric extrapolation factors to derive a human equivalent NOAEL or LOAEL. Various uncertainty factors are then applied to operationally derive the RfC. A draft

methodology and minimal verification criteria for the RfC are available in "Interim Methods for Development of Inhalation Reference Doses, U.S. EPA, 1989 (EPA/600/8–88/066F).

Assuming the RfCs applicable to fuel and fuel additive emissions could be derived from Tiers 1 and 2 information, they could potentially be used to determine testing needs. For example, if exposures were in the vicinity of or significantly above the RfC, the emissions would be considered to have toxic potential and Tier 3 would probably be invoked. If exposures were substantially lower than the RfC, public health concerns would generally be allayed. However, the RfC methodology would not remove the need to temper these conclusions with expert scientific judgment. For example, if the adverse health effects appeared severe or exhibited the potential to progress significantly with duration of exposure, and if the potentially exposed population were large, then signficant concern might persist even if preliminary estimates of the exposure levels were low relative to the RfC. Comments are requested concerning the possible application of the RfC methodology to Tier 3 decision-making in the proposed program.

3. Potential Tier 3 Testing Requirements

To be most cost-effective, Tier 3 testing would be designed to specifically address data gaps regarding the endpoints of concern. Thus, Tier 3 requirements could potentially include further emission characterization procedures, perhaps involving additional vehicles, to identify and quantify harmful emission products with greater precision. Higher-order modeling calculations or exposure field studies could be required to resolve uncertainties in the Tier 1 emissions exposure information. Health effects testing requirements would be aimed at providing sufficient information to make sound conclusions about the degree of health risk. If more than one endpoint were of concern, EPA would attempt to reduce testing costs by permitting combined protocols and/or inhalation exposures insofar as possible. Emission characterization or health effects testing using emissions generated from miscalibrated vehicles or under other non-FTP conditions might sometimes be included.

For a quantitative risk assessment, health effects test exposures would be chosen to permit the determination of a NOAEL and LOAEL. While Tiers 1 and/or 2 may provide some of this information, Tier 3 would typically require NOAEL or LOAEL determinations for longer duration exposures or additional endpoints. If chronic inhalation studies are required, they would generally be preceded by subchronic range-finding studies. These would avoid the possibility of designing a chronic inhalation test with exposure levels so high that excessive mortality occurs or so low that a LOAEL is not identified. Depending on the endpoints under evaluation, consideration would also be given to including a mid-duration examination in the case of chronic inhalation tests. A mid-duration evaluation would be useful for affirming the adequacy of exposure levels and, in some cases, might enable interim risk conclusions to be drawn which would avoid the need for further examination. Inhalation studies would generally make use of rodent species, but higher order mammals might occasionally be required.

While Tier 3 testing requirements would be targeted to critical areas of concern, EPA would also exercise its judgment to avoid the false economy of establishing overly narrow requirements. Just as requirements for too many assays would be wasteful of resources, requirements for too few assays might result in inconclusive findings, creating needs for still further testing at greater total expense than would have been necessary at the start. Similarly, EPA would consider the value of including secondary evaluations as useful and low-cost adjuncts to tests already required. For example, if the histopathology of a specified target organ were the primary examination required at the conclusion of an inhalation exposure, other organs could be weighed and saved in storage for a limited time period, at low incremental expense. If indicated, these other organs would then be available for subsequent examination, avoiding the possible need to repeat the chronic inhalation procedures to assess the effects on these other organs.

Because the specific health testing requirements which would be imposed in Tier 3 would be tailored to individual circumstances, precise test guidelines cannot be provided in advance. However, some of the likely testing scenarios which might be required in Tier 3 are cited below. Where possible, existing TSCA guidelines for these tests are referenced. It should be recognized, however, that such guidelines might need to be revised to accommodate emission inhalation requirements and/or to evaluate certain structures or functions which the current guidelines do not adequately address. Study parameters which might require modification include exposure routes and concentrations, species selection, number of animal subjects, examination procedures and frequencies, and analytic requirements. Furthermore, interim advances in the underlying science and testing technology may provide superior approaches which could be available for use by the time Tier 3 requirements would be implemented.

Tier 3 follow-up for mutagenicity and carcinogenicity concerns raised in Tiers 1 and 2 would often include a cancer bioassay of chronic duration (e.g., 40 CFR 798.3300 or 798.3320). However, this would generally be preceded by short-term studies to investigate the mechanisms involved and, in some cases, these shorter tests might be sufficient to allay concerns or clarify the nature of the risks. Among these possibilities is a mutagenicity battery, which might include a biochemical specific locus test, bacterial DNA damage or repair tests, and heritable translocation test (40 CFR 798.5195, 798.5500, and 798.5955). Newer procedures, such as cell transformation, DNA adducts, and gene amplification, would also be considered. In addition, physiologically-based pharmacokinetic (PBPK) or metabolic studies (e.g., 40 CFR 798.7100) might be required.

Tier 3 evaluation of reproductive and developmental toxicity would generally involve two generation breeding studies (40 CFR 798.4700) and/or reproductive assays by continuous breeding (RACB) [25]. Each of these approaches entails approximately 9–12 months of exposure.

Additional evaluation for neurotoxicity might include metabolic analyses (40 CFR 798.7100), subchronic neurotoxicity (including histopathology) tests (40 CFR 798.6400), and/or one- to two-year chronic inhalation tests (e.g., 40 CFR 798.3260). Such studies might involve neurobehavioral, neurochemical, pharmacokinetic, and/or histopathological assessments. Because fetuses and infants may be particularly sensitive to neurotoxicants, special studies involving in-utero and neonatal exposures might be indicated.

The follow-up required for pulmonary toxicity concerns would frequently involve subchronic and/or chronic inhalation studies (40 CFR 798.2450 and 798.3260), emphasizing histopathology of the respiratory tract. If indicated, pulmonary function measurements, host

[25] A protocol developed by the National Toxicology Program of the National Institute of Environmental Health Sciences is available in the public docket.

defense assays, immunotoxicity tests, and enzyme assays of lavage cells and fluids might be required in conjunction with these exposures. If both chronic toxicity and carcinogenesis were of concern, then a combined protocol (40 CFR 798.3320) would be in order.

Tier 3 testing to follow up on Tier 1 findings would depend on the specific identified concerns. EPA anticipates that such concerns, identified by previous scientific studies in the literature or by the occurrence of known toxic chemicals in the emissions, would most often pertain to potential hepatic, renal, or endocrine toxicity, but effects on other organ systems or physiologic processes are also possible. Potential testing might include metabolic, subchronic exposure, and/or chronic exposure studies (40 CFR 798.7100, 798.2450, and/or 798.3260), but specialized functional, immunologic, and enzyme studies might also be required.

As previously mentioned, Tier 3 requirements could also include additional work to improve the exposure estimates submitted in compliance with Tier 1. The need for additional exposure data would depend in part on the limitations of the Tier 1 estimates, and in part on the nature of the associated health effects information. That is, highly precise and accurate exposure information would not be cost effective if the health assessment were based on limited and/or uncertain results, and vice versa.

The approach which EPA plans to use in determining the potential need for greater precision and accuracy in the exposure information is to consider the slope of the toxic response. If the slope is steep within the range of potential human exposures, then a small change in exposure is likely to have a major impact on the eventual risk assessment. Greater precision would thus be required in the exposure calculation. If adverse health effects appear likely within the projected range of exposures, improved estimates might also be needed to determine the conditions and locations under which these exposures might occur as well as the size of the potentially affected populations. On the other hand, if only minor health effects occur at levels well above ambient concentrations and only a relatively small number of people are likely to be exposed, then additional refinements of the exposure calculations would not be warranted.

Tier 3 exposure assessment could include physical monitoring studies or the application of more sophisticated modeling techniques, some of which are described in Section VI.B.2. However, the precise nature of these studies would be strongly influenced by interim advances that are expected in the growing science of exposure assessment. The general topic of gasoline exposure is receiving increased attention by the scientific community as a topic for research, in recognition of the limited knowledge base currently available for determining the risks from mobile source emissions and from the use of motor vehicle fuels.[26] Thus, new information and new scientific methodologies for monitoring and estimating population exposures are expected to emerge in a time frame which will be useful for guiding the types of exposure assessments which might be required at the Tier 3 level.

EPA requests comments on the possible scenarios and test guidelines outlined above, and solicits suggestions on other health effect and exposure studies which should be considered. An alternative approach for determining Tier 3 testing requirements would permit the responsible manufacturers to propose testing scenarios which would address the areas of concern identified by EPA as requiring Tier 3 follow-up evaluation. Such proposals would be subject to review and approval by EPA scientists prior to their implementation by the manufacturer in compliance with Tier 3. Comments are requested about this alternative approach.

VII. Reporting Requirements

The materials to be submitted to EPA following completion of all Tier 1 and Tier 2 requirements are divided into three major categories: Basic registration data, a summary report, and appendices. Producers who must conduct additional testing under Tier 3 will be required to submit a final report when the designated Tier 3 testing is complete. The nature of the information to be included in each reporting category is described below.

A. Basic Registration Data

The information mandated by existing regulations under section 211(b)(1) must be submitted (or resubmitted) individually for each product being registered, using EPA forms which are in effect at the time of the submittal. This requirement pertains to all previously registered fuels and additives, including relabeled products, as well as those for which first-time registration is sought. However, if the basic registration data previously submitted for an existing fuel or additive is accurate and complete, then a statement asserting that this is so will suffice in lieu of the submittal of duplicate information. A finding by EPA that this information is not, in fact, accurate and complete as claimed will result in the report being considered inadequate.

The basic information currently required for fuel and additive registration includes product and manufacturer identification, concentration and purpose-in-use, and specific compositional data. In addition to these items, information on the production volume of each product will be required. If the producer has participated in group efforts to satisfy Tier 1 and Tier 2 requirements for the product, then identifying information for the group must also be provided. Similarly, if the producer is relying on another manufacturer's (or group's) previous registration materials in compliance with the testing requirements for a new product, then the other manufacturer and product (or group) must be identified. In addition, the producer must certify and provide evidence that the first manufacturer has been notified.

B. Summary Report

This document will provide a text summary of the evaluation procedures, results, and conclusions pertaining to Tiers 1 and 2. A cover page should be included, identifying the subject product, the manufacturer's name and address, and a designated contact person and phone number. For group submissions, all products and manufacturers to which the report pertains must be named, and a contact person, address, and phone number for the group must be identified. If a group submission has been prepared under the aegis of a trade or other umbrella organization, this organization must also be identified. The body of the summary report should be divided into the following sections:

1. Executive Summary

This should consist of a brief description of the general results and conclusions of Tier 1 and Tier 2 activities, emphasizing information and test data which provide evidence for potential adverse health and/or welfare effects.

2. Tier 1 Report

This section of the summary report is intended to provide an overview of the information provided by Tier 1. Detailed procedural descriptions, tables, and other outputs are to be included in the appendices.

Literature search. The search methods should be described, including the identity of data bases, search terms, and

[26] Journal of Exposure Analysis and Environmental Epidemiology, January–March, 1992.

time periods accessed. Any in-house and/or other unpublished studies included in the literature search should also be described briefly. The results and conclusions of the literature search with respect to potential health and welfare effects of the subject fuels/additives should be summarized. If test documentation provided by the literature search has been used to satisfy some or all of the other program requirements, the relevant studies should be discussed and their adequacy to fulfill the specific purposes of the associated program requirements should be justified. Finally, the person(s) or contractors conducting the search are to be identified.

Emission generation and characterization. This section of the summary report should identify the vehicle selected and describe the procedures followed in vehicle preparation and maintenance and in the generation, storage, and processing of emissions for testing. A description of the analytic methods used to characterize the fuel/additive emissions products should also be provided. Problems encountered in generating and/or characterizing the emissions should be discussed, including attempts to resolve the problems and their potential effects on testing outcomes. The laboratories performing these procedures should be identified.

Modeling. The underlying principles, functions, and limitations of the chosen modeling or other analytic methods should be explained, and a summary of results and conclusions provided.

3. Tier 2 Report

For each study, the objectives, principles, and general procedures should be outlined and the findings and conclusions summarized. Discussion should be included regarding problems encountered during the performance of the tests and the methods used to resolve them. This discussion should include the impact which such problems may have had on the study outcomes.

4. Conclusions

Further testing needs should be identified or else a discussion should be provided explaining why the results of Tiers 1 and 2 should not trigger Tier 3 testing requirements.

C. Appendices

Detailed information in support of the general discussions contained in the summary report are to be submitted as appendices to that report. In regard to the literature search, the appendices will contain (1) summary tables, using the format for Table IV suggested within the draft petition process guidelines associated with the air toxics program (available in Central Docket Section A-130, EPA Docket No. A-90-48), (2) a complete printed copy of reference lists and associated abstracts obtained from database searches, (3) complete documentation of in-house studies and other unpublished information sources, and (4) complete documentation (e.g., copies of journal articles) of previous studies which are being cited in satisfaction of emission characterization and/or Tier 2 test requirements. Appendices to the emission characterization section will contain detailed protocols, copies of all relevant laboratory reports, a list of all speciated emission products and their emission rates, and documentation of calibration/verification procedures. For the section on modeling methods, an appendix should be provided for detailed calculations and results.

An appendix is also required for each of the tests conducted in compliance with Tier 2 requirements. These appendices should contain the full detailed study protocol, complete laboratory report, statistical analysis of the findings, and scientific conclusions. These materials should conform to the reporting requirements of the individual study guidelines as well as the general standards for record keeping and reporting specified in 40 CFR part 792, subpart J. A final appendix should be provided, containing laboratory certifications and associated personnel credentials.

D. Tier 3 Report

Reports for additional tests required under the provisions of Tier 3 should include a cover page with identifying information as described above for the Tier 1 and 2 summary report. The report should begin with discussion of the concerns arising under the previous tiers which led to the Tier 3 requirements, the specific objectives of the additional studies, and a summary of pertinent results and conclusions. This summary discussion should be supported with appendices containing the kinds of documentation discussed above with respect to Tier 2: Full protocols, lab reports, statistical analyses, discussion of problems and findings, and conclusions. The laboratory conducting the required tests must be identified, and relevant certifications and personnel credentials provided.

VIII. Special Provisions

A. Exemption for Relabeled Products

A company's product is registered as "relabeled" if it is simply a repackaged and rebranded version of a formulation which is also registered by the original manufacturer. As previously discussed, requiring companies which sell relabeled products to conduct the health and welfare effects assessments proposed in today's rulemaking would clearly duplicate the efforts of the original manufacturer. Thus, under the authority of section 211(e)(3)(C), which provides that the Administrator may exempt from the rule any fuel or fuel additive upon a finding that any testing of that fuel or fuel additive would be duplicative of adquate existing testing, relabeled products will be exempt from the evaluation and testing requirements of the registration program. For relabeled products, only basic registration information will be required, as described above in section VII.A. Of course, this presumes that the registration requirements proposed in this NPRM would be satisfied for the original product by the original manufacturer.

Among the total of 1,160 manufacturers with one or more registered fuel additives as of mid-1990, over half (604) registered only relabeled additives, and will therefore not be required to comply with the health and welfare effects assessment provisions of the registration program. Relabeled additives account for approximately 30 percent of all additive products currently registered.

B. Applicability of Evaporative Emission Testing

As discussed fully in section III.C, requirements for the chemical characterization and toxicologic testing of evaporative emissions are proposed to apply only to those fuels and additives for which vaporization is expected to be significant. Fuels which are supplied by way of sealed containment and engine delivery systems would thus be exempt from evaporative emission requirements, as would liquid fuels with RVP less than 2.0 psi. Methane, propane, and diesel fuels would be exempt from evaporative emissions testing under this guideline.

The proposed criteria for determining the applicability of evaporative emission testing requirements to additives are based on (1) the change in RVP of the appropriate additive/base fuel mixture relative to the RVP of the base fuel alone, and (2) the partial pressure of the additive in the additive/base fuel mixture. If the presence of the additive does not increase the RVP of the base fuel by at least 0.1 psi, and if the partial pressure of the additive in the additive/fuel mixture in the vapor phase at 100

degrees Fahrenheit and atmospheric pressure is less than 0.1 psi, then evaporative emission testing would not need to be performed.

C. Small Business Provisions

Section 211(e) grants EPA discretionary authority to provide program exemptions, deferments, or modifications for small businesses. However, in developing the proposed registration program, EPA has carefully balanced the desire for rigorous scientific evaluation with consideration for the associated costs, and has included a number of provisions designed to decrease the cost burdens to all manufacturers. These general cost-reduction provisions include: (1) The tiered program structure which imposes rigorous testing requirements only when needed to further explicate significant identified concerns, (2) the opportunity to share program costs and burdens with other manufacturers, (3) the ability to rely on existing adequate information for compliance with testing requirements, (4) the exemption for relabeled products, and (5) the general reliance on existing regulatory programs for evaluating potential emission control system effects. In consideration of these provisions, EPA is not initially proposing to implement the authority to make special allowances for small businesses.

EPA's economic analyses indicate that the financial impact of the proposed program on most fuel and fuel additive producers would be relatively modest. The median cost per producer is estimated to be about $2,000 for compliance with Tiers 1 and 2. Furthermore, the costs for about 85 percent of small fuel companies and 70 percent of small additive companies (as defined by the Small Business Administration) would be less than $10,000. Nevertheless, the estimated total costs per manufacturer vary widely, from about $500 to over $2 million, depending on each manufacturer's number and type of products and opportunities for cost-sharing with manufacturers of similar products. Thus, as one might expect, the financial impact of the proposed program could be significant for some small companies.

As discussed further in section XIV, below, a Regulatory Flexibility Analysis conducted by EPA indicates that small fuel producers would not be jeopardized by the proposed rule, but that nearly six percent of small additive manufacturers (about 1.5 percent of all fuel/additive manufacturers) might experience financial distress. However, size alone does not predict which additive manufacturers would be adversely affected, and EPA has not yet been able to identify what, if any, common factors place certain small companies at risk. Further analysis is expected to clarify these factors and, if appropriate, EPA may elect to implement special provisions for such companies in the final rule.

Various alternative provisions are under consideration for this purpose. First, the vulnerable companies could be excused from one or more of the program's requirements. For example, they could be excused from all Tier 2 biological testing or could be required to conduct only those Tier 2 tests which address the endpoints mandated by statute (carcinogenicity, mutagenicity, and teratogenicity). Another alternative would be to require only the Tier 1 literature search for such companies. To ensure that no small additive companies would be financially stressed by the regulations, complete program exemptions might be necessary. However, the potential health and environmental effects associated with an additive product are generally not related to the size of its producer, and EPA does not favor this alternative. On the other hand, because risk is partly a function of exposure, and potential exposure to an additive's emissions is related to the volume produced and sold, appropriate measures of volume in conjunction with other relevant financial parameters may be reasonable to consider in determining possible small business allowances.

Public comment is requested concerning these small business issues and alternative ideas for possible small business allowances or exemptions.

D. Possible Exemption for "De Minimis" Factors

EPA is considering the creation of program exemptions for certain fuel additives which are expected to have only a *"de minimis"* impact on the composition and biological effects of motor vehicle emissions. These exemptions are contemplated under two sets of circumstances, described below. EPA requests comment on each of these possible exemptions.

The first exemption under consideration would relate to additives which are recommended for use at less than 2,500 ppm maximum concentration in fuel and which fall into the "baseline conventional" categories described above in section IV. Because the elemental composition of these additives is the same as their associated base fuels, and because some degree of emissions variability is inevitable, it may be extremely difficult to distinguish the emission products or the emissions-based biological effects of these additives (as mixed in base fuel) from the emission products or effects of the base fuel alone. These factors are reflected in the proposed grouping scheme, in which baseline conventional additives and fuels are grouped together and share the same representatives. However, an argument can be made that test requirements for these additives would be duplicative of the requirements for the related fuels, and that a testing exemption for the additives might be justifiable under section 211(e)(3).

If the exemption for baseline conventional additives were put into effect, then the second exemption possibility would arise. This potential exemption would apply to those additives in the "atypical" formulation classes (see section IV) which had such small concentrations of the atypical components that their emission products could be judged to be of negligible toxicologic significance. The specific concentration criterion for this exemption could be established by assuming that the toxicity of the atypical component was similar to that of a known toxic agent (e.g., lead or benzene) and then estimating the maximum concentration of such a toxicant which would result in an insignificant exposure risk.

Comments are solicited in regard to possible exemptions under these *"de minimis"* circumstances. Suggestions for the specific concentration which could be used as the threshold for granting atypical additive exemptions, and the underlying rationale for selecting that threshold, are also welcome.

E. Possible Temporary Exemption for Experimental Fuels and Fuel Additives

As part of the August 7, 1990 ANPRM for this action, EPA requested comment on whether special provisions should be included for low volume fuels and additives. In general, commenters on the ANPRM did not support a long term or permanent exemption for low production volume fuels/additives due to equity and public health considerations.

Nevertheless, EPA believes that, under certain circumstances, a temporary exemption for low production volume, experimental fuels and additives may be appropriate, similar to the provisions for experimental chemicals under the Toxic Substances Control Act (TSCA). Authority for this possible provision would be based on CAA section 211(e)(3)(A), which permits EPA to exempt, defer, or modify the program requirements for any small

business, with "small business" to be defined within the regulations. Given that compliance costs for this proposed program could exceed a million dollars for new or unique fuels and additives, the proposed testing and evaluation requirements could pose a substantial barrier to innovation and development at a time when both environmental and energy concerns are generating significant public and private sector interest and activity in this area.

Thus, EPA requests comments on the possibility of providing a temporary program exemption or deferment for experimental fuels and additives. Eligibility for this possible exemption would be limited to new products, i.e., those which were not registered as of the effective date of the final rule or, if already registered, had not yet been placed into wholesale or retail commerce. Instead of meeting the program requirements immediately, the interested producer would apply to EPA for a deferment. The application would provide details on the chemical, physical, and functional properties of the fuel or additive involved, the purpose of the requested temporary exemption, the anticipated volume of use, and the expected toxicity and exposure related to the product and its combustion and evaporative emissions. Information required under 40 CFR 723.50 covering exemptions for Premanufacture Notification under TSCA would also be required. The temporary exemption would require EPA approval following submittal of the application and review by EPA.

The temporary exemption would be available only when the use of the fuel or additive was restricted to experimental (research, development, and evaluation) purposes. No product in commercial application, i.e., wholesale or retail sale, would be eligible for the deferment of testing requirements. In addition, a volume limitation could be established. For example, the exemption could apply only to experimental fuels not exceeding, say, 500,000 pounds per year or experimental additives not exceeding 2,500 pounds per year of production or consumption. Alternatively, similar to 40 CFR 720.36 and 40 CFR 790.42(a)(5) promulgated under TSCA, no volume limit would be placed on production and use, provided that the use of the fuel or additive was restricted to experimental purposes. The temporary exemption would be good for a period of 5 years after the exemption was approved by EPA, but would expire if the annual use exceeded any potential volume limitations or if the product was offered for wholesale or retail sale. EPA asks comment on whether additional annually renewable exemption periods should be permitted. Comment is also requested on whether volume restrictions should be established and, if so, what limitations would be most appropriate.

IX. Compliance Considerations

As discussed above, the Tier 1 and Tier 2 information proposed in this rulemaking must be submitted prior to registration in the case of fuels and fuel additives which are not registered on the date of promulgation of the final regulations (expected June 1, 1993). Fuels and additives already registered on the date of promulgation must comply with the regulations within three years following the effective date of the final rule. If further testing and information submittal is required under Tier 3 provisions, a separate timetable would be established for compliance with such requirements.

Failure to comply with the requirements of the rule could result in revocation of a product's registration. In addition, direct financial penalties are specified in section 211(d) of the statute. According to this provision, persons who fail to submit any information or conduct any tests required by the Administrator under section 211(b) shall be liable to the United States for a civil penalty of not more than $25,000 for every day of such violation plus the amount of economic benefit or savings resulting from the violation. Each day after the due date for submission of data shall constitute a separate day of violation. Civil penalties shall be assessed in accordance with sections 205(b) and (c), which permit EPA to proceed either in court or in an administrative action. In addition, the district courts of the United States have jurisdiction to compel the furnishing of information and the conduct of tests required under section 211(b).

EPA would consider failure to submit information, or submission of information that does not comply with the requirements of this rule, to constitute a violation of sections 211 (b) and (e). If a group of manufacturers commits to performing joint testing, each manufacturer would separately be in violation of the rule. However, the Administrator would retain the authority to remit or mitigate any penalty.

Because EPA recognizes that unusual circumstances outside the control of the manufacturer may occasionally interfere with the ability to comply with all of the provisions of the rule, the proposed regulations contain mechanisms to allow manufactuers to request modification of the requirements. However, EPA expects persons subject to this rule to submit comments about the feasibility of the proposed testing requirements during the comment period, and does not intend the modification process to be used in place of such commentary. Instead, the purpose of the proposed modification process is to allow only persons who experience unforeseen difficulties or accidents in conducting the needed tests to request modification of the requirements in order to avoid being in violation of the rule. However, section 211(e) requires the requisite (Tier 1 and Tier 2) information to be submitted to EPA for previously registered products within three years after the effective date of the rule. Accordingly, EPA proposes that modification requests must be submitted as soon as the manufacturer is aware of the difficulty, thus prohibiting persons from waiting until the deadline before informing EPA of circumstances which might prevent EPA from receiving the data on time.

X. Confidential Business Information

A provision under section 211(b)(2) states that the results of health effects tests "conducted in conformity with test procedures and protocols established by the Administrator" shall not be considered confidential. Thus, information supplied to EPA in compliance with testing requirements will be available to the public. However, the statute specifically differentiates between health effects test data and other information submitted for registration. Thus, data on product composition and other registration information not integral to the testing program will continue to be held in confidence.

XI. Public Participation

EPA strongly encourages full public participation in its decision-making processes. In addition to those areas where specific comment has been requested, EPA solicits comments on all aspects of today's proposal from all interested parties. Whenever applicable, full supporting rationale, data, and detailed analyses should also be submitted to allow EPA to make maximum use of the comments. Commenters are encouraged to provide specific suggestions for improvements to any aspect of the proposal, especially in regard to modifications which could reduce the costs and burdens of fuel and fuel additive registration without unduly compromising the scientific accuracy of the program or compliance with the statutory intent. All comments should be

directed to the EPA Air Docket Section, Docket No. A–90–07 (see "ADDRESSES"). Comments will be accepted for 30 days after the public hearing (see "DATES" and "SUPPLEMENTARY INFORMATION" in section I).

XII. Statutory Authority

The statutory authority for this proposal is provided by sections 205(b) and (c), 211, and 301(a) of the Clean Air Act as amended (42 U.S.C. 7524(b) and (c) 7545, and 7601(a), Public Law 95–95).

XIII. Administrative Designation and Regulatory Analysis

Under Executive Order 12291, EPA must judge whether a regulation is major and therefore subject to the requirement that a Regulatory Impact Analysis (RIA) be prepared. Major regulations are defined to be those which have an annual impact on the economy of $100 million or more, have a significant adverse impact on competition, investment, employment, or innovation, or result in a major price increase for the affected product.

A regulatory support document which presents EPA's analysis of the costs and economic impacts of the proposed rule is available for review in the public docket. EPA estimates that the costs to industry for submittal of the proposed requisite data for Tiers 1 and 2 would total approximately $83 million incurred over the first three year period after promulgation of the final rule. Thus, the average annual cost during this period would be about $27 million. In the subsequent three years, Tier 3 requirements might cost an additional $10 million annually. These projected overall costs are far less than the $100 million annual cost criterion which defines a "major rule". Also, the proposed rule would not be expected to significantly impact competition, investment, employment, or innovation, or result in major price increases in the industry.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB and any EPA response to OMB's comments are available in the public docket for this rulemaking.

While the costs of the proposed program would be expected to vary widely between various fuel/additive groups and amoung individual manufacturers, a hypothetical example may help to clarify the proposed scope, time frame, and costs of the program. Based on the analysis provided in the regulatory support document, a possible testing scenario and the associated compliance costs for a hypothetical group of products is discussed below and summarized in Figure 6. These costs would pertain to the evaluation and testing of a fuel selected to represent the hypothetical group. The total costs would subsequently be shared by all of the manufacturers with products enrolled in the group. The requirements and costs assume that the group consists of 40 fuels and additives which contain no "atypical" elements, that the group does not qualify for exemption from evaporative emission testing, and that adequate existing studies are not available to fulfill any of the speciation or biological test requirements. Therefore, under this hypothetical situation, all of the potential requirements of Tiers 1 and 2 must be conducted. Combustion emission generation procedures are assumed to be performed using one light-duty vehicle, for both emission characterization and biological testing purposes.

FIGURE 6: HYPOTHETICAL COST SCENARIO

	Cost
Tier 1 requirements	
Data Research and Analysis	$16,500
Vehicle Costs	32,500
Combustion Emission Generation/Speciation	27,000
Evaporative Emission Generation/Speciation	4,000
Total Tier 1 Costs	80,000
Tier 2 requirements	
Combustion Emission Generation	59,000
Biological Tests on Combustion Emissions	294,000
Evaporative Emission Generation	16,000
Biological Tests on Evaporative Emissions	286,000
Total Tier 2 Costs	655,000
Administrative and Reporting Costs	157,000
Total Tier 1, Tier 2, Administrative Costs	892,000
Estimated Costs of Tier	32–2,500,000
Total Costs	3–3,500,000

Under this scenario, the cost of conducting all requirements of Tier 1 is estimated at approximately $80,000. Of this, EPA estimates data research and analysis (literature search and data modeling) costs to be about $16,500, and vehicle-related costs (acquisition/operation/mileage accumulation) to be about $32,500. EPA estimates a cost of $27,000 for generation and speciation of combustion emissions, and approximately $4,000 for generation and speciation of evaporative emissions.

Further, EPA estimates the costs of conducting all Tier 2 test requirements to total nearly $655,000 under this hypothetical example. Including set-up costs, combustion emission generation costs are estimated at about $59,000, while biological testing of combustion emissions is estimated at nearly $294,000. The cost of generating adequate evaporative emissions to conduct all Tier 2 screening tests would be approximately $16,000, and conducting Tier 2 tests on these emissions is estimated to cost $286,000.

The administrative costs for organizing and administering the group and for reporting the Tier 1 and 2 results to EPA is judged to be nearly $157,000. Adding this to the Tier 1 and Tier 2 costs provided above yields a total cost of approximately $892,000 for the group as a whole. Assuming these costs are incurred over a three-year period and are divided equally among the 40 products in the group, the cost to a manufacturer with a single product in this group would be about $7,300 annually for three years, or $22,000 in total.

Let us assume further that, within 18 months of receiving the group's report, EPA determines that the submittal is complete and that the required Tier 1 and 2 evaluations have been adequately performed. However, a number of health concerns are raised by the results. The literature search suggests a high potential for toxic liver effects to be caused by chronic exposure to the combustion emissions of fuels similar to those in the group, and the Tier 2 results indicate a need for further evaluation of possible carcinogenic and pulmonary effects of three emissions. In addition, a large and widespread population is expected to be exposed to the emissions of products in this group. Thus, EPA determines that more rigorous testing is necessary under Tier 3 to clarify the potential risks posed by this group of products.

Under this hypothetical scenario, two tests are likely to be required to address the identified areas of concern: A two-year combined chronic toxicity/carcinogenicity study conducted in two species, and a metabolism study to elucidate the potential carcinogenic mechanisms. The group is given three years in which to complete these tests. The total cost, including costs for emission generation and biological testing, is estimated at 2 to 2.5 million dollars. When divided equally among the 40 products in the group and spread over the three-year compliance period, the Tier 3 testing cost per product in this

group would be in the range of $17–21,000 annually for three years.

In sum, EPA estimates that the total costs to this hypothetical group would range from approximately 3 to 3.5 million dollars, incurred over a seven or eight year time period. The total cost for each product would range from about $75,000 to $87,500, averaging about $10–12,000 per year. EPA seeks comments on these estimates, given such a scenario.

The above discussion illustrates the compliance costs which the proposed program might entail for a group of fuel/additive producers. However, the proposed program could have some indirect cost implications, as well. For example, if the costs of compliance represented a significant barrier to entry into the fuel/additive marketplace, real social costs (including potential environmental costs) could be incurred as a result of delayed or deterred innovation. These potential social costs have not as yet been quantified, and EPA requests comment, along with supporting data, on how to evaluate and quantify such indirect impacts of the program.

XIV. Compliance with Regulatory Flexibility Act

Under section 605 of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, the Administrator is required to assess the economic impact of this proposed regulation on small business entities. Accordingly, a Regulatory Flexibility Analysis (RFA) has been prepared and is available in the public docket. The RFA compares the estimated financial effects of the proposed programs on large and small companies as defined by the Small Business Administration.

Using weighted average financial statistics based on a sample of current fuel and additive manufacturers, the RFA analyzes the impacts of the proposed program by projecting the effects which the estimated compliance costs would have on each company's return on assets (ROA). For both fuel and additive producers, the analysis shows that changes in ROA directly attributable to the proposed regulations would be greater for small companies than large ones. On the average, small companies tend to have lower compliance costs than large companies, but this tendency is outweighed by the relatively greater vulnerability of small companies resulting from their much lower levels of assets and earnings.

Among fuel manufacturers, these ROA effects do not appear to have a significant impact. Only two small fuel producers in the sample would experience a reduction in ROA by as much as one percent, and none would be driven into severe financial distress or closure. Among additive manufacturers, however, the impacts of the proposed regulations appear more significant. While the impacts on large additive companies would be extremely minor, the analysis projects that 23 (almost six percent) of small additive companies might experience a reduction in ROA to less than 2.5 percent, which is indicative of financial stress. In addition, 18 small companies might be pushed into severe financial distress ($ROA < -4$ percent), and two into closure ($ROA < -30$ percent). Additional analysis will be needed to identify the specific factors which cause this subset of small additive companies to be at particular financial risk. Potential allowances for small businesses are discussed above in section VIII.C.

XV. Compliance with the Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* An information Collection Request document has been prepared by EPA (ICR No. 309.06) and a copy may be obtained from Sandy Farmer, Information Policy Branch; EPA; 401 M St., SW. (PM–223Y); Washington, DC, 20460 or by calling (202) 260–2740.

Public reporting burden for this collection of information is estimated to vary from 1 to 1,768 hours per response with an average of 440 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing the collection of information.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch; EPA; 401 M St., SW., (PM–223Y); Washington, DC, 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC, 20503, marked "Attention: Desk Officer for EPA". The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects in 40 CFR Part 79

Fuel, Fuel additive, Gasoline, Motor vehicle pollution, Penalties, Incorporation by reference.

Dated: April 1, 1992.

William K. Reilly,

Administrator.

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